D.D.N.J., F.D.C. 8241–8280 Issued January 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8241–8280

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *January 11, 1966.*

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795-933—66

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8241. (F.D.C. No. 50805. S. Nos. 70–401/2 V, 30–422 A, 30–425/7 A, 30–703 A, 30–705 A.)

INFORMATION FILED: 1–19–65, S. Dist. Ohio, against **Carl W. Elliott (truck stop employee), Chillicothe, Ohio.**

CHARGE: Between 2–11–63 and 4–15–64, *amphetamine sulfate tablets* were dispensed 8 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–3–65. Imprisonment for 2 years.

8242. (F.D.C. No. 50478. S. Nos. 30–924/5 A, 30–927 A.)

INFORMATION FILED: 9–9–64, E. Dist. Ky., against **George H. Hoer, Southgate, Ky.**

CHARGE: Between 3–13–64 and 3–30–64, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–8–65. $300 fine, plus costs.

8243. (F.D.C. No. 50487. S. No. 54–454 X.)

INFORMATION FILED: 10–19–64, E. Dist. Ky., against **Nellie Hager (waitress), Newport, Ky.**

CHARGE: On 11–2–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–10–65. $100 fine suspended, and probation for 1 year.

8244. (F.D.C. No. 50808. S. Nos. 86–056/7 A, 87–726/8 A, 87–737/8 A.)

INFORMATION FILED: 1–20–65, Dist. N.J., against **Edward Allaire, t/a Ed's Trading Center, Kearny, N.J.**

CHARGE: Between 5–6–64 and 8–25–64, *amphetamine sulfate tablets* were dispensed 7 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–9–65. 2 years in jail and probation for 3 years.

8245. (F.D.C. No. 50606. S. No. 73–001 X.)

INFORMATION FILED: 10–26–64, Dist. Colo., against **Donald L. Noyes (truck stop employee), Denver, Colo.**

CHARGE: On 12–3–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–23–65. $500 fine, and probation for 2 years.

8246. **(2 criminal actions.)** (F.D.C. Nos. 48921; 49164. S. Nos. 54–706 V, 54–712 V; 46–909 X.)

INFORMATIONS FILED: 6–10–63 and 10–29–63, W. Dist. Mo., against **Robert P. Parker, Van Buren, Ark.**

CHARGE: Between 1–31–63 and 4–30–63, *amphetamine sulfate tablets* were dispensed twice without a prescription at Joplin, Mo.; and on 6–11–63, *amphetamine sulfate tablets* were dispensed once without a prescription at Joplin, Mo.

PLEA: Not guilty.

DISPOSITION: On 6–10–64, the cases came on for trial before court and jury; and on 6–11–64, the jury returned a verdict of guilty. On 1–22–65, Parker was sentenced to imprisonment for 90 days and probation for 2 years.

8247. (F.D.C. No. 49166. S. No. 44–571 T.)

INFORMATION FILED: 9–24–63, Dist. N.J., against **John Esposito (operator of a cleaning service on the premises of a truck stop), Jersey City, N.J.**

CHARGE: On 5–1–62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–26–65. Imprisonment for 1 year.

8248. (F.D.C. No. 50470. S. Nos. 30–914 A, 30–936 A, 30–983/4 A.)

INFORMATION FILED: 10–8–64, E. Dist. Ky., against **Sylvester Murphy (taxi driver), Newport, Ky.**

CHARGE: Between 1–17–64 and 3–30–64, *amphetamine sulfate tablets* were dispensed twice, and *Nembutal Sodium capsules* and *Dexamyl Spansule capsules* were dispensed once each, without a prescription.

PLEA: Guilty.

DISPOSITION: 3–8–65. $400 fine, plus costs.

8249. (F.D.C. No. 50184. S. Nos. 14–841/3 T, 14–859 T, 14–961/2 X.)

INFORMATION FILED: 8–12–64, N. Dist. Ill., against **Jess Willard Shoulders, t/a Jesse Shoulders, Calumet City, Ill.**

CHARGE: Between 2–1–62 and 10–22–63, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: On 11–30–64, the defendant was sentenced to 6 years in prison, which was suspended, and he was placed on probation for 5 years. On 3–8–65, a petition for the revocation of probation was filed alleging that the defendant had dispensed *secobarbital sodium capsules* 3 times and *choral hydrate* once without a prescription. A hearing was held on 3–9–65, after which the court revoked the defendant's probation and ordered that the suspended sentence be served.

8250. (F.D.C. No. 50378. S. Nos. 14–970/1 X.)

INFORMATION FILED: 8–3–64, N. Dist. Ind., against **Betty O'Bannon (bartender), Hammond, Ind.**

CHARGE: On 10–31–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court on 3–16–65. At the conclusion of the trial, the court found the defendant guilty. On 4–13–65, the defendant was sentenced to probation for 2 years.

8251. (F.D.C. No. 50349. S. Nos. 257 X, 1–919 X, 1–924 X.)

INFORMATION FILED: 9–29–64, N. Dist. Ga., against **Ernest Ballew, t/a Ballew's Service Station, Gainesville, Ga.**

CHARGE: Between 7–29–63 and 7–30–63, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court and jury from 10–22–64 to 10–23–64, and was concluded when the jury reported that they were unable to reach a verdict. The case again came to trial on 4–20–65, before the court and jury and was concluded on 4–21–65, with a verdict of guilty. The defendant was placed on probation for 2 years.

8252. (F.D.C. No. 50459. S. No. 22–871 X.)

INFORMATION FILED: 10–26–64, Dist. Colo., against **Billy C. Blankenship (truck stop employee), Denver, Colo.**

CHARGE: On 9–13–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–23–65. $200 fine, and probation for 2 years.

8253. (F.D.C. No. 50373. S. No. 22–893 X.)

INFORMATION FILED: 9–22–64, Dist. Colo., against **Charles Hazen Sample (truck stop operator), and Kenneth Griffith (truck stop attendant), Commerce City, Colo.**

CHARGE: On 12–13–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–23–65. Sample—$500 fine, and probation for 2 years; Griffith—$500 fine, and probation for 2 years.

8254. (F.D.C. No. 51047. S. No. 138–501 A.)

INFORMATION FILED: 3–5–65, Dist. Colo., against **George I. Meseraull, Denver, Colo.**

CHARGE: On 12–30–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–7–65. $1,000 fine, suspended, 6 months in correctional institution, and probation for 6 months.

8255. (F.D.C. No. 50823. S. Nos. 87–734 A, 87–739 A.)

INFORMATION FILED: 1–21–65, Dist. N.J., against **William Pauser, t/a J & J Truck Stop, Whitehouse, N.J.**

CHARGE: Between 8–10–64 and 8–25–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–17–65. $1,000 fine.

8256. (F.D.C. No. 50793. S. Nos. 26–169/70 X.)

INFORMATION FILED: 3–5–65, E. Dist. Mich., against **Leonard D. Slepski (pharmacist), Detroit, Mich.**

CHARGE: On 2–27–64, *amphetamine sulfate tablets* and *Enovid tablets* were each dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 6–23–65. Fine of $750, and probation for 2 years.

8257. (F.D.C. No. 51048. S. No. 14–501 B.)

INFORMATION FILED: 3–4–65, Dist. Colo., against **Reinold L. Swanson, Denver, Colo.**

CHARGE: On 1–2–65, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–24–65. $1,000 fine, and 6 months in jail.

8258. (F.D.C. No. 50817. S. No. 85–282 A.)

INFORMATION FILED: 2–12–65, Dist. Del., against **Edward E. Coleman, Jr. (pharmacist), New Castle, Del.**

CHARGE: On 1–22–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–13–65. Probation for 2 years.

8259. (F.D.C. No. 51241. S. Nos. 34–344/5 A.)

INFORMATION FILED: 6–7–65, S. Dist. Ohio, against **Rudy Harmon, Columbus, Ohio.**

CHARGE: On 7–18–64, *amphetamine sulfate tablets* and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–5–65. $500 fine, and probation for 2 years.

8260. (F.D.C. No. 49547. S. Nos. 67–493 V, 67–495 V, 2–578/9 X, 65–831 X, 65–843 X, 65–846 X, 65–983/5 X.)

INFORMATION FILED: 2–18–64 and 3–2–64, S. Dist. Ga., against **M. Eugene King, t/a King's Truck Stop, Darien, Ga.**

CHARGE: Between 4–26–63 and 12–17–63, *amphetamine sulfate tablets* were dispensed 6 times, *dextro-amphetamine sulfate tablets* were dispensed 3 times, and *methamphetamine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–10–64. 2 years in prison.

8261. (F.D.C. No. 49870. S. Nos. 36–162/3 X.)

INFORMATION FILED: 5–15–64, E. Dist. La., against **Willis Ray Spencer, Jefferson Parish, La.**

CHARGE: Between 10–7–63 and 10–16–63, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: On 8–20–64, the case came on for trial by the court and after one day of trial the court found the defendant guilty. On 10–17–64, the defendant was sentenced to imprisonment for 1½ years and fined $500.

8262. (F.D.C. No. 50343. S. Nos. 15-216/17 X, 15-235/36 X, 16-396 X, 17-045 X.)

INFORMATION FILED: 8-14-64, S. Dist. Ohio, against **George K. Whitacre, t/a Whitacre's Pharmacy No. 2, Springfield, Ohio.**

CHARGE: Between 7-25-63 and 8-8-63, *dextro-amphetamine sulfate tablets* were dispensed 3 times, *Equanil tablets* were dispensed twice, and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-19-65. $1,200 fine.

8263. (F.D.C. No. 50638. S. Nos. 91-468/9 X.)

INFORMATION FILED: 3-19-65, Dist. Md., against **Jay Royce Brinsfield, t/a Sun Pharmacy, Rising Sun, Md.**

CHARGE: On 12-4-63, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4-23-65. $150 fine.

8264. (F.D.C. No. 50819. S. Nos. 74-083/86 A, 74-088/89 A.)

INFORMATION FILED: 3-1-65, N. Dist. Ala., against **Harry Jackson McRae (pharmacist), Tuscaloosa, Ala.**

CHARGE: Between 5-21-64 and 5-25-64, *Dexedrine Sulfate tablets* were dispensed 5 times and *Miltown tablets* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 3-22-65. $500 fine.

8265. (F.D.C. No. 51032. S. No. 68-522 A.)

INFORMATION FILED: 3-1-65, Dist. Minn., against **James Reynold Kaufmann, Richfield, Minn.**

CHARGE: On 6-3-64, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-14-65. Imprisonment for 1 year.

8266. (F.D.C. No. 50628. S. Nos. 22-793 X, 43-102 A, 43-104 A.)

INFORMATION FILED: 3-22-65, Dist. Utah, against **Hyland Pharmacy, Inc., Salt Lake City, Utah, and Douglas E. Roth (president, manager, and pharmacist).**

CHARGE: Between 12-14-63 and 1-22-64, *Dexedrine Sulfate tablets* were dispensed twice and *V-Cillin K tablets* were dispensed once upon request for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 4-26-65. Corporation—$1,500 fine, $1,000 of which was suspended; Roth—imprisonment for 6 months and 1 day, suspended, and $1,500 fine, $1,000 of which was suspended.

8267. (F.D.C. No. 50020. S. Nos. 86-270 V, 242 X.)

INFORMATION FILED: 7-21-64, N. Dist. Ga., against **Harold Woodie, Atlanta, Ga., and Leonard Roy Woods, Jr., Atlanta, Ga.**

CHARGE: Between 4–2–63 and 6–5–63, *desoxyephedrine hydrochloride tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Woodie—guilty; Woods—nolo contendere.

DISPOSITION: 4–22–65. Woodie—probation for 2 years. 3–22–65. Woods—probation for 2 years.

8268. (F.D.C. No. 50186. S. Nos. 86–278/80 V.)

INFORMATION FILED: 9–29–64, N. Dist. Ga., against **Henry Lee Gee, Gainesville, Ga., and Thomas Franklin Stephens, Lawrenceville, Ga.**

CHARGE: 4–21–63, *desoxyephedrine hydrochloride tablets, desoxyephedrine hydrochloride capsules,* and *amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 4–20–65. At the conclusion of the trial, the jury returned a verdict of guilty on all 3 counts. On 4–29–65, the defendants were sentenced as follows: Gee—6 months in jail suspended, and probation for 2 years; Stephens—6 months in jail.

8269. (F.D.C. No. 50781. S. Nos. 30–642/5 A, 30–647 A.)

INFORMATION FILED: 1–13–65, E. Dist. Ky., against **Garry C. Rice (clinic employee), Wittensville, Ky.**

CHARGE: Between 1–18–64 and 2–10–64, *desoxyephedrine hydrochloride tablets* were dispensed 3 times and *Tuinal capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–28–65. 90 days in jail.

8270. (F.D.C. No. 50795. S. Nos. 38–341 X, 38–343 X, 73–407/8 A, 73–721 A.)

INFORMATION FILED: 1–4–65, S. Dist. Ala., against **Edward T. McBride (pharmacist and partner in a drug store), Selma, Ala.**

CHARGE: Between 11–21–63 and 3–4–64, *Equanil tablets* were dispensed once, *Dexedrine Sulfate tablets* were dispensed once, and *Miltown tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–2–65. $500 fine.

8271. (F.D.C. No. 50344. S. Nos. 15–191 X, 15–215 X, 15–218/19 X, 16–978 X.)

INFORMATION FILED: 8–14–64, S. Dist. Ohio, against **Robert W. Whitacre, t/a Whitacre's Pharmcy No. 1, Springfield, Ohio, and Robert S. Clingman (pharmacist).**

CHARGE: Between 7–11–63 and 7–25–63, *Equanil tablets* were dispensed 4 times and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty by Whitacre to 3 counts; by Clingman to 2 counts.

DISPOSITION: 2–19–65. Whitacre—$500 fine; Clingman—sentence suspended.

8272. (F.D.C. No. 50345. S. Nos. 15–187 X, 15–194 X, 15–206 X, 15–224 X, 16–391 X, 16–947 X, 16–956 X, 17–051 X.)

INFORMATION FILED: 8–14–64, S. Dist. Ohio, against **Joseph O. Whitacre, t/a Whitacre's Pharmacy No. 3, Springfield, Ohio.**

CHARGE: Between 7–11–63 and 9–5–63, *Equanil tablets* were dispensed 5 times and *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–19–65. $500 fine.

8273. (F.D.C. No. 50352. S. Nos. 15–192 X, 15–226 X, 16–402 X, 16–924 X, 16–936 X, 16–964/5 X, 17–048 X.)

INFORMATION FILED: 8–14–64, S. Dist. Ohio, against **Howard E. Whitacre, t/a Whitacre's Pharmacy No. 4, Springfield, Ohio, and John A. Snyder (pharmacist).**

CHARGE: Between 6–4–63 and 7–30–63, *Equanil tablets* were dispensed 6 times without a prescription and *Prednis tablets* were dispensed twice upon request for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty by Whitacre to 6 counts; by Snyder to 2 counts.

DISPOSITION: 2–19–65. Whitacre—$1,600 fine; Snyder—sentence suspended.

8274. (F.D.C. No. 50789. S. Nos. 31–081 A, 31–083 A, 31–085/8 A, 31–090/2 A.)

INFORMATION FILED: 12–23–64, E. Dist. Ky., against **William A. Rose, t/a W. A. Rose Drug Co., Prestonsburg, Ky., and Ralph Sherman (pharmacist).**

CHARGE: Between 1–17–64 and 2–11–64, *Librium Hydrochloride capsules*, and *thyroid tablets* were dispensed 3 times each, *penicillin tablets* were dispensed twice, and *reserpine tablets* were dispensed once without a prescription.

PLEA: Guilty to 9 counts by Rose; guilty to 6 counts by Sherman.

DISPOSITION: 4–26–65. Rose—$900 fine, plus costs; Sherman—$600 fine, of which $500 was suspended, and probation for 1 year.

8275. (F.D.C. No. 50362. S. Nos. 6–423/4 X, 6–426 X, 6–762 X, 56–025 V.)

INFORMATION FILED: 1–25–65, Dist. Mass., against **Professional Pharmacy, Inc., Fall River, Mass., and Russell C. Ouellette (president).**

CHARGE: Between 5–24–63 and 7–19–63, *Librium Hydrochloride capsules* were dispensed 3 times, and *Dexedrine Sulfate tablets* were dispensed twice upon request for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 4–26–65. Corporation—$100 fine; Ouellette—$100 fine.

8276. (F.D.C. No. 50474. S. Nos. 31–001/12 A.)

INFORMATION FILED: 9–22–64, E. Dist. Ky., against **Aelic M. Short, t/a Short Drug Store, Pikeville, Ky.**

CHARGE: Between 1–17–64 and 1–27–64, *Librium Hydrochloride capsules* were dispensed 5 times, *penicillin tablets* were dispensed 4 times, *reserpine tablets* were dispensed twice, and *thyroid tablets* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 4–26–65. $600 fine, plus costs, and probation for 1 year.

8277. (F.D.C. No. 46395. S. Nos. 32–462/3 R, 33–563/5 R, 33–570/71 R.)

INFORMATION FILED: 7–16–63, S. Dist. N.Y., against **Gilbar Pharmacy, Inc., Yonkers, N.Y., and Alexander Giller (president), and Leonard Barnett (secretary-treasurer).**

CHARGE: Between 3–1–60 and 3–31–60, *Chloromycetin capsules* were dispensed 3 times without a prescription; and *dextro-amphetamine sulfate capsules* and *secobarbital sodium capsules* were each dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty by the corporation to 7 counts; and by Giller and Barnett each to two counts involving the dispensing of dextro-amphetamine sulfate capsules and secobarbital sodium capsules.

DISPOSITION: 4–14–64. Corporation—$1,000 fine; each individual—probation for 1 year.

8278. (F.D.C. No. 49174. S. Nos. 53–693/4 V.)

INFORMATION FILED: 1–8–64, Dist. Oreg., against **Edward John Grite (partner in a drug store), Portland, Oreg.**

CHARGE: On 1–4–63, *Nembutal Sodium capsules* and *Amytal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–26–64. $2,000 fine, and probation for 1 year.

8279. (F.D.C. No. 50626. S. Nos. 31–021/32 A.)

INFORMATION FILED: 12–15–64, E. Dist. Ky., against **William M. Huffman, t/a Huffman Drug Store, Pikeville, Ky.**

CHARGE: Between 1–17–64 and 2–18–64, *penicillin tablets* were dispensed 9 times, *Librium Hydrochloride capsules* were dispensed twice, and *prednisone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–26–65. $600 fine, plus costs, and probation for 1 year.

8280. (F.D.C. No. 50376. S. Nos. 16–882 X, 16–884/90 X.)

INFORMATION FILED: 2–12–65, E. Dist. Tenn., against **Fred T. Hilbert, t/a Hilbert's Drug Store, Jonesboro, Tenn.**

CHARGE: Between 7–23–63 and 9–24–63, *prednisone tablets* were dispensed 4 times, *Diuril tablets* were dispensed 3 times, and *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: On 4–5–65, not guilty to all counts; on 5–25–65, nolo contendere to 7 counts.

DISPOSITION: On 4–14–65, upon the defendant's plea of not guilty, the trial of the case began before court and jury. On 4–20–65, the case was submitted to the jury and on 4–21–65, the jury found the defendant not guilty of the charge involving the dispensing of penicillin. However, the jury had been unable to arrive at a verdict on the other counts. When, after further deliberation by the jury, no verdict was reached, the court declared a mistrial on 7 other counts. On 5–25–65, upon a plea of nolo contendere to such 7 counts, the court fined the defendant $1,800 and placed him on probation for 15 months.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8246, 8250, 8251, 8261, 8268, 8280) Prosecution contested.
[2] (8249) Violation of probation.

[1] (8246, 8250, 8251, 8261, 8268, 8280) Prosecution contested.
[2] (8249) Violation of probation.

ERRATUM

Change Drug and Device Notice of Judgment No. 8070 to read as follows:

INFORMATION FILED: 7–15–64, S. Dist. Fla., against **A. & F. R. Corp., t/a Westwood Lake Pharmacy, Miami, Fla., and Sidney M. Margolis (pharmacist).**

[1](8246, 8250, 8251, 8261, 8268, 8280) Prosecution contested.

U.S. GOVERNMENT PRINTING OFFICE: 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8281–8340

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent or trial by the court and appeal, and in which a seized device in one case and portions of seized articles in two cases were not condemned and were released; and (2) a criminal proceeding which was terminated upon a plea of guilty, and including a revocation of probation proceeding. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 16, 1966.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 8282, 8291, 8293, 8334; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 8291, 8292; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 8282, 8291, 8293; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 8295; cosmetic actionable under the drug provisions of the Act, No. 8334.

212-853—66——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8281–8340

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(e)(1)(A)(ii), the article was a drug, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the established name of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or some other antibiotic drug or some derivative thereof, and was not from a batch with respect to which certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8281. Tempain (dipyrone). (F.D.C. No. 50327. S. Nos. 2–235 A, 3–174 A.)

QUANTITY: 248 30-cc. vials of dipyrone for injection and 296 16-oz. btls., and 16 1-gal. btls., of dipyrone liquid, at Tampa, Fla.

SHIPPED: Between 1–28–64 and 2–1–64, from Chicago, Ill., by Medical Chemicals Corp., and from Greenville, S.C., by Libby, Edwards & Brown, Inc.

LABEL IN PART: (Vial) "Tempain 50 Per Cent Solution W/V Each cc. contains: Methampyrone Sodium 0.5 Gram in water for injection * * * Caution: Federal law prohibits * * * Dosage * * * Warning * * * Sole Distributor Crest Pharmaceuticals, Inc. Tampa 9, Florida"; (btl.) "Tempain Each Teaspoonful (5 cc.) contains Dipyrone 500 Mg. (Methampyrone Sodium) (Non-Narcotics Antipyretic-Analgesic) Caution: Federal law prohibits * * * Sole Distributor Crest Pharmaceuticals, Inc. Tampa 9, Florida Indications: For the relief of pain and/or lowering temperature. Dosage: For the relief of pain, 1 to 5 teaspoonful every two to four hours."

ACCOMPANYING LABELING: Package insert entitled "Tempain."

LIBELED: 7–8–64, M. Dist. Fla.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements which represented and suggested that the article had a wide range of dosage; that side effects were minimal and mild; and that it enjoyed advantages of the absence of any serious side effects; that the drug stopped aches and pains with most gratifying results; which statements were false and misleading as applied to a drug for which there were serious hazards attendant to its use; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, since the article was a prescription drug and its labeling failed to contain, as required by regulations, adequate information for use including indications, effects, dosages, routes, methods, and frequency and duration of administration and relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to administer the drug can use it safely and for the purposes for which it was intended; and 502(j)—the dipyrone liquid was dangerous to health, when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested, in the labeling.

DISPOSITION: 8–8–64. Consent—claimed by Crest Pharmaceuticals, Inc., and relabeled.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

8282. Various prescription drugs. (F.D.C. No. 46257. S. Nos. 69–492/500 R, 69–600 R.)

QUANTITY: Unknown quantities of repacked and unrepacked prescription drugs, at Mount Prospect, Ill., in possession of Keefer's Pharmacy.

SHIPPED: On unknown dates, from outside the State of Illinois, by various drug handlers.

LABEL IN PART: (Some drugs) "Caution: Federal law prohibits dispensing without a prescription," "Sample: Not To Be Sold," "Professional Sample Not To Be Sold," "Physicians Professional Sample," "Clinical Package Not To Be Sold," "Clinical Trial Supply," "Physician Sample," Professional Sample," and "Caution: New Drug—Limited By Federal Law To Investigational Use."

LIBELED: 8–16–61, N. Dist. Ill.; libel amended 5–13–63.

CHARGE: 502(a)—while held for sale, the sample legends on the labels of a number of the articles were false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not to be sold" samples for physicians

and others lawfully engaged in dispensing prescription drugs; 502(a)—the words "Caution: New Drug—Limited By Federal Law To Investigational Use" on the labels of a number of the articles were false and misleading as applied to articles then in possession of a repacker and intended for sale and not then intended for investigational use; 502(b)(1)—the labels of a number of the repacked articles failed to contain the name and place of business of the manufacturer, packer or distributor; 502(e)(2)—a number of the repacked articles were fabricated from two or more ingredients and the labels of those articles failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of a number of the repacked articles failed to bear adequate directions for use, since their labels failed to bear the quantity of dose, frequency, time, and method of administration, the preparation for use, and an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations; 503(b)(4)—the labels of a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—a number of the articles were new drugs within the meaning of 201(p), for which applications were not effective as required by 505; and 502(a)—the labeling of such new drugs which represented the drugs to be suitable for use in treatment of disease was false and misleading as applied to such drugs for which new-drug applications were no longer effective.

DISPOSITION: On 10–2–61, J. T. Keefer, Mount Prospect, Ill., filed a claim to certain articles attached under the libel of information. On 8–3–64, upon the agreed motion of the parties, the court ordered that the repacked drugs and those drugs bearing the investigational use legend as their labels, be condemned and destroyed; and that the unrepacked drugs whose labels bore the sample legends and did not bear the investigational use legends, be returned to the claimant.

8283. Various repacked prescription drugs. (F.D.C. No. 46073. S. Nos. 96–401/10 R.)

QUANTITY: Approximately 360 containers, at Philadelphia, Pa., in possession of Zackian Bros. Pharmacy, a partnership.

SHIPPED: On unknown dates, from various firms outside the State of Pennsylvania.

LABEL IN PART: (Some containers) "Zackian Bros. Pharmacy Rx 27 S. 60th Street Philadelphia 39, Pa."

RESULTS OF INVESTIGATION: The articles had been repacked by the dealer into bottles labeled with such brand names for the drugs as were indicative of their manufacture outside the State of Pennsylvania; except one new drug, repacked by the dealer, which contained active ingredients manufactured in the State of New Jersey.

LIBELED: 7–10–61, E. Dist. Pa.

CHARGE: All of the drugs, 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot number as required under regulations.

Various certifiable antibiotic drugs, 502(l)—the articles were represented as drugs composed in part of a derivative of chlortetracycline, and they were

not from a batch with respect to which a certificate or release was effective pursuant to 507 since they were in a repackaged condition and had not been certified since repacking.

Some of the drugs, 503(b)(4)—the article were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

One or more of the drugs, 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: On 8–18–61, Zackian Bros. Pharmacy, a partnership, Philadelphia, Pa., filed a claim to the articles, and filed an answer, denying that the various articles of drug were misbranded. On 11–6–61, the Government served written interrogatories upon the claimant. On 7–5–62, the Government filed a motion for a default decree, alleging that the answers to its written interrogatories had not been received. On 7–27–62, the claimant filed answers to the Government's written interrogatories. Thereafter, the Government filed a motion to compel further and more complete answers to its written interrogatories and for joint inspection of the seized drugs. On 10–31–62, the court granted the Government's motion and authorized a joint inspection by the Government and the claimant of the seized drugs. On 7–22–63, the claimant consenting without admitting or denying any of the allegations of the libel, the court entered a consent decree of condemnation providing for disposition as prescribed by the Food and Drug Administration.

8284. Time disintegration capsules. (F.D.C. No. 50216. S. No. 48–128 A.)

QUANTITY: 1 ctn., containing approximately 12,000 capsules, and 1 repacked btl. of 1,000 capsules, at Livonia, Mich.

SHIPPED: 1–21–64, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Ctn.) "Shaw Formula CC–P Capsules—Pyrilamine Maleate 25 Mg. Phenylpropanolamine HCl. 25 Mg. Prophenpyridamine Maleate 10 Mg. Phenylephrine HCl. 10 Mg. Each capsule is so prepared that the drugs are released over a period of approximately 8 to 10 hours—Mfg. for Detroit Pharm. Co. Manufactured by Shaw Pharmacal Co.—St. Louis 15, Mo."

RESULTS OF INVESTIGATION: The bottled capsules had been shipped as above, in bulk, and had been repacked locally.

LIBELED: 6–2–64, E. Dist. Mich.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 7–23–64. Default—destruction.

8285. Myotrate capsules. (F.D.C. No. 50076. S. No. 84–409 A.)

QUANTITY: 21 100-capsule btls. and 9 100-capsule btls., at St. Louis, Mo.

SHIPPED: 12–17–63, from St. Louis, Mo., by Shaw Pharmacal Co., in bulk to Marshall, Ill., where the article was repacked into bottles by Sig Laboratories, Inc. On 4–29–64, Sig Laboratories, Inc., reshipped the repacked article to St. Louis, Mo.

LABEL IN PART: (Btl.) "Myotrate 45 MG. Delacaps * * * each Delacap Contains 45 Mg. Pentaerythritol Tetranitrate Dosage: One Delacap on Arising * * * Control 6580."

LIBELED: 5–1–64, E. Dist. Mo.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since it was a prescription drug which was a new drug and its labeling bearing the information for its use, as prescribed by regulations, was not labeling authorized by an effective new-drug application; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application was effective with respect to such article.

DISPOSITION: 8–14–64. Default—destruction.

8286. **Pentaerythritol tetranitrate capsules.** (F.D.C. No. 50240. S. No. 31–766 A.)

QUANTITY: 64,100 capsules in 3 bulk drums at Dayton, Ohio.

SHIPPED: 1–16–64, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Drum) "Shaw—T.D. Pentaerythritol Tetranitrate 80 Mg. Capsules—Dosage: One Capsule Daily—Caution: Federal Law—Mfg. For Superior Pharmacal Co. Manufactured By Shaw Pharmacal Co. * * * St. Louis, Mo."

LIBELED: 6–25–64, S. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application was effective with respect to such drug.

DISPOSITION: 8–14–64. Default—destruction.

8287. **Infa-Soy formula.** (F.D.C. No. 50574. S. No. 30–498 A.)

QUANTITY: 496 cases, each containing 12 15½-oz. cans, at San Leandro, Calif.

SHIPPED: 8–3–64, from Madison, Tenn., by Madison Laboratories.

LABEL IN PART: (Can) "Infa-Soy A Hypoallergenic Infant Soy Formula * * * Each can of Infa-Soy formula * * * supplies Vitamins * * * Minerals * * * Directions * * * Infa-Soy concentrated liquid is designed for use by allergic infants, treatment of duodenal ulcers, and other metabolic diseases in which whole animal milk should not be used. * * * Madison Laboratories Madison, Tennessee A Division of Nutrition International Corporation."

LIBELED: 9–11–64, N. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and adequate directions for use for the layman could not be written for the diagnosis and treatment of allergic infants, treatment of duodenal ulcers, and other metabolic diseases in which whole animal milk should not be used; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of a new-drug application filed pursuant to law was effective with respect to such drug.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–7–64. Default—destruction.

8288. **Infa-Soy formula.** (F.D.C. No. 50568. S. No. 61–788 A.)

QUANTITY: 2,309 cases, each containing 12 15½-oz. cans, at La Sierra, Calif.

SHIPPED: 6–26–64, from Madison, Tenn., by Madison Laboratories.

LABEL IN PART: (Can) "Infa-Soy A Hypoallergenic Infant Soy Formula * * * Each can of Infa-Soy formula * * * supplies Vitamins * * * Minerals * * * Directions * * * Infa-Soy concentrated liquid is designed for use by allergic infants, treatment of duodenal ulcers, and other metabolic diseases in which whole animal milk should not be used. * * * Madison Laboratories Madison, Tennessee A Division of Nutrition International Corporation."

LIBELED: 9–4–64, S. Dist. Calif.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application pursuant to 505(b) was effective with respect to such drug; and 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use, and adequate directions for use for the layman could not be written for the diagnosis and treatment of allergic infants, treatment of duodenal ulcers, and other metabolic diseases in which whole animal milk should not be used.

The libel alleged also that the article, while held for sale, was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–23–64. Default—destruction.

8289. **"Act" tablets.** (F.D.C. No. 50316. S. No. 85–319 A.)

QUANTITY: 1,797 vials of 15 tablets each, at Trenton, N.J.

SHIPPED: 1–21–63, from Philadelphia, Pa., by Jan Laboratories, Inc.

LABEL IN PART: (Vial) "15 Tablets Act as an aid in decreasing fatigue and the discomfort of hangover and headaches, and in increasing work efficiency. Manufactured for Cherie Company Trenton, New Jorsey * * * Each tablet contains: Caffeine Alk 300 mg., Ephedrine Sulf. 11 mg., Magnesium Ox. 100 mg., Lactose 14 mg. Dosage."

LIBELED: 6–30–64, Dist. N.J.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, in that no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 7–28–64. Default—destruction.

DRUG FOR VETERINARY USE

8290. **Cardiobee 15.** (F.D.C. No. 49884. S. No. 1–972 A.)

QUANTITY: 20 ctns., each containing 100 10-cc. unlabeled vials, and 136 10-cc. labeled vials, at Hialeah, Fla.

SHIPPED: Between 8–29–63 and 12–11–63, from Chicago, Ill.

LABEL IN PART: (Vial) "Multiple Dose Sterile Vial Cardiobee 15 Each 10 cc. contains: Diisopropylamino-Dichlorethanoate * * * For Veterinary Use Only Indications * * * distributed by Zirin Laboratories Int'l., Inc., Miami 48, Florida."

ACCOMPANYING LABELING: Price lists and product description booklets entitled "Zirin their health is our only business."

RESULTS OF INVESTIGATION: The article had been shipped in unlabeled vials contained in cartons which were labeled, in part, "Compound #492," and the

above label had been applied to some of the vials by Zirin Laboratories International, Inc., Hialeah, Fla., after their receipt. Zirin Laboratories International, Inc., had on hand additional quantities of the vial labels which they intended to apply to the unlabeled vials, and had on hand the above accompanying labeling which they used in promoting sales of the article.

LIBELED: 3–5–64, S. Dist. Fla.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: On 3–31–64, Zirin Laboratories International, Inc., Hialeah, Fla., filed a claim and an answer denying that the article was a new drug, and moved for the removal of the cause on the ground that jurisdiction was vested in the Eleventh Judicial Circuit Court of Florida pursuant to the Florida food, drug and cosmetic law; however, on a subsequent date, this motion was denied by the court. On 5–5–64, the claimant served on the Government its request for admissions and, on 5–28–64, an answer to this request for admissions was served on the claimant by the Government. On 6–17–64, the Government served written interrogatories on the claimant and, on 7–6–64, the claimant filed answers to the Government's written interrogatories; thereafter, the Government filed supplemental written interrogatories.

The claimant filed its motion to dismiss the libel for failure to answer its interrogatories but, on 12–7–64, the court denied this motion. On 12–15–64, the claimant filed a motion for an order authorizing sales of a product similar to the product seized, pending the final disposition of the cause, but, on 1–4–65, the court denied this motion on the ground that the claimant was under no injunction or restraining order issued by the court which had arisen from this case and the claimant, in effect, had improperly sought a declaratory decree as to a matter not before the court. On 4–19–65, a consent decree of condemnation was filed and the court ordered the destruction of the article.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED*

8291. **Various prescription drugs.** (F.D.C. No. 46451. S. Nos. 2–005/12 T, 2–016 T, 2–019 T, 2–020 T, 2–022 T.)

QUANTITY: 450 various size drug items, at Columbus, Ga., in possession of Lee Drug Co. of Georgia, Inc.

SHIPPED: On unknown dates, from various drug handlers outside the State of Georgia.

LABEL IN PART: (Some drugs) "Sample," "Professional Sample," and "Physician's Sample."

RESULTS OF INVESTIGATION: Some of the articles had been repacked by the Lee Drug Co. of Georgia, Inc., and some of the articles had not yet been repacked.

LIBELED: 9–29–61, M. Dist. Ga.

CHARGE: 502(a)—while held for sale, the words "Sample," "Professional Sample," "Physician's Sample," and similar wording on the labels of the articles, were false and misleading as applied to the articles in possession of a repacker and intended for sale and not then intended for use as "complimentary—not for

*See also No. 8283.

sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(l)—some of the articles were composed in part of a derivative of penicillin, streptomycin, chlortetracycline, chloramphenicol or bacitracin and were not from a batch with respect to which a certificate or release had been issued; 502(b)—some of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(e)(1)—some of the articles were not designated solely by a name recognized in an official compendium and their labels failed to bear the common or usual names of the drugs; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use; and 503(b)(4)—some of the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–15–61. Default—destruction.

8292. **Various prescription drugs.** (F.D.C. No. 49963. S. Nos. 19–386/90 A.)

QUANTITY: 8,000 pkgs. of approximately 250 different drugs, at Pittsburgh, Pa., in possession of Samuel Heyden, t/a Craig-Forbes Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Professional Sample."

RESULTS OF INVESTIGATION: Some of the articles had been repacked by the Craig-Forbes Pharmacy, and some of the articles had not been repacked.

LIBELED: 4–17–64, W. Dist. Pa.

CHARGE: 502(a)—while held for sale, a number of the articles bore on their labels the statement "Professional Sample" and similar sample-legend statements, which statements were false and misleading as applied to articles intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(2)—a number of the articles were drugs in package form and they failed to bear a label containing an accurate statement of the quantity of contents; 502(f)(1)—a number of the articles failed to bear labeling containing adequate directions for use and they were not exempt from such requirement since they were prescription drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations; 502(f)(1)—a number of the repacked articles were new drugs subject to 505 and they failed to bear labeling containing adequate directions for use and they were not exempt from such requirement since the labeling on or within the packages of the articles was not the labeling required by regulations, namely, the labeling authorized by the new-drug applications effective with respect to the articles prior to their repacking; 502(l)—a number of the repacked articles were represented as drugs composed wholly or in part of a kind of antibiotic drug or a derivative thereof and they were not from batches with respect to which certificates or releases were effective with respect to the repacked drugs; 502(l)—a number of the articles were represented as drugs composed wholly or in part of a kind of antibiotic drug or a derivative thereof and they were not from batches with respect to which certificates or releases issued were effective since the drugs had passed their expiration dates; and 503(b)(4)—a number of the articles were drugs subject to 503(b)(1) and their labels failed to

bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: On 4–27–64, Samuel Heyden, t/a Craig-Forbes Pharmacy, Pittsburgh, Pa., filed an answer denying that the drugs were misbranded, and, on 6–23–64, filed a claim to the drugs. Thereafter, the claimant served written interrogatories upon the Government. On or about 8–5–64, the Government filed its answers to the claimant's written interrogatories. Thereafter, it was determined that the sample-legend drugs in their original containers were not misbranded under 502(a) by reason of the sample legends and should be released to the claimant unless misbranded under the other provisions of the law as alleged in the libel. In accordance with such determination the court, on 9–20–64, ordered that the drugs which were found to be misbranded, be condemned and that the other seized drugs be returned to the claimant. On 10–5–64 the court ordered that the condemned drugs be destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

8293. Various prescription drugs. (F.D.C. No. 48618. S. Nos. 14–281/95 V.)

QUANTITY: Unknown quantities in various containers, at Chicago, Ill., in possession of Humboldt Medical Supply, Inc.

SHIPPED: On unknown dates, by various drug handlers, from outside the State of Illinois.

LABEL IN PART: (Some labels) "Physician's Sample," "Physician's Professional Package," "Physicians Sample Not To Be Sold," or similar wording, and (some labels) the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Illinois, and (some labels) the words "Physician's Sample" or similar wording, and (some labels) the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

The articles also consisted of quantities of prescription drugs which were not yet repacked, consisting of unknown quantities of prescription drugs in containers to which labels were affixed bearing such brand names as were indicative of their manufacture outside the State of Illinois, and (some labels) the words "Professional Sample" or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 1–31–63, N. Dist. Ill.; libel amended on or about 9–30–63.

CHARGE: 502(a)—while held for sale, the sample legends on the labels of a number of the articles (repacked and unrepacked) were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the repacked articles failed to bear a label containing the name or place of business of the manufacturer, packer, or distributor; 502(e)(1)—a number of the repacked articles were not designated solely by a name recognized in an official compendium and their labels failed to bear

*See also Nos. 8282, 8283, 8291, 8292.

the common or usual name of the drug; 502(e)(2)—a number of the articles were drugs not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of a number of the repacked articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the articles as required by regulations; 502(f)(1)—a number of the articles were new drugs, the labeling of which failed to bear adequate directions for use since the packages containing such articles were the packages from which they were to be dispensed and the labeling on or within such packages bearing the information for the use of such drugs as required by regulations was not the labeling authorized by the new-drug applications which were effective with respect to such drugs prior to their repacking; and 503(b)(4)—a number of the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Humboldt Medical Supply, Inc., claimant, having failed to answer the interrogatories served upon it on 9–30–63, a default judgment or forfeiture and destruction was entered on 3–10–64.

8294. Liver concentrate and iron capsules. (F.D.C. No. 49763. S. No. 13–666 A.)

QUANTITY: 39 50-capsule btls. at Fall River, Mass.

SHIPPED: On unknown date prior to 1959, from St. Louis, Mo.

LABEL IN PART: (Btl.) "Each Capsule Contains: * * * 0.33 mg. Folic Acid * * * Adult dose—2 to 3 capsules three times daily before meals."

LIBELED: 2–11–64, Dist. Mass.

CHARGE: 503(b)(4)—while held for sale, the article was subject to 503(b)(1) by reason of its folic acid content, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–30–64. Default—destruction.

8295. Adelgadina tablets. (F.D.C. No. 48864. S. No. 40–000 V.)

QUANTITY: 420 40-tablet btls. at Santurce, P.R.

SHIPPED: 2–14–63, from Miami, Fla., by Tarmac Interamerican, Inc.

LABEL IN PART: (Btl. and ctn.) "Adelgadina Anorexiante en Dietas de Adelgazamiento y Complemento Multivitaminico Formula Cada Gragea Contiene: Sulfato de d-anfetamina 0.005 Gm. Clorhidrato de Tiamina (Vitamina B_1) 1.0015 Gm. Vitamina B_{12} 4 micrograms Bitartrata de Colina 0.100 Gm. Dl-Metionina 0.050 Gm. Riboflavina (Vitamina B_2) 0.0005 Gm. Piridoxina (Vitamina B_6) 0.0003 Gm. Pantotenato de Calcio 0.0015 Gm. Carboximetilcelulosa 0.150 Gm. Excipiente C.S.P. 0.380 Gm. Tarmac Products Inc. * * * New York, N.Y." and (ctns. only) "Caution: Federal law prohibits dispensing without prescription."

ACCOMPANYING LABELING: Carton inserts reading in part "Adelgadina (Tabletas Para Adelgazar) * * * Tarmac Products, Inc. * * * New York, N.Y."

LIBELED: 6–7–63, Dist. P.R.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article had no contraindications, and that it prevented fat accumulation thereby avoiding obesity; 502(c)—the information required to appear on the label of the bottle carton under 503(b)(4), in the Spanish language, namely, the statement "Caution: Federal law prohibits dispensing without prescription" was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since it was written in the English language; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since the labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications and side effects and precautions under which practitioners could use the drug safely and for the purpose for which it was intended, including all the purposes for which it was advertised or represented; and 503(b)(4)—in that it was a drug subject to the provisions of 503(b)(1) and the bottle label failed to bear the statement [in Spanish] "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–13–63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

8296. Dipyrone injection. (F.D.C. No. 50302. S. No. 70–821 A.)

QUANTITY: 984 unlabeled 30-cc. btls., at Minneapolis, Minn., in possession of Physicians & Hospital Supply Co.

SHIPPED: 4–10–64, from Detroit, Mich.

ACCOMPANYING LABELING: Label reading in part "Narone * * * Each cc. contains 500 mg. dipyrone * * * for injection * * * Dosage: 3 to 5 cc. repeat as required"; and package insert entitled "Ulmer Narone (Dipyrone) amidopyrine derivative."

RESULTS OF INVESTIGATION: The unlabeled bottles were in trays; the bottles, in the course of the dealer's business operations, were to be cartoned and were to have the above accompanying labeling applied.

LIBELED: 6–19–64, Dist. Minn.

CHARGE: 502(a)—while held for sale, the package insert contained statements which represented and suggested that the article might be used as a substitute for narcotics without the common side effects and addiction liability of narcotics, which statements were misleading as applied to an article which exhibited serious untoward effects; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since the article was a prescription drug and its labeling failed to contain, as required by regulations, adequate information for use including relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law could administer the drug safely and for the purposes for which it was intended.

*See also Nos. 8281–8283, 8285, 8287, 8288, 8291–8293, 8295.

DISPOSITION: 6–26–64. Consent—claimed by Physicians & Hospital Supply Co., Minneapolis, Minn., and labeled with new labeling.

8297. **Dipyrone injection.** (F.D.C. No. 50400. S. Nos. 80–823/4 A.)

QUANTITY: 60 ctns., each containing 10 30-cc. vials, at Mineola, N.Y.

SHIPPED: 4–13–64 and 5–18–64, from Pennasauken, N.J., by Generic Drugs, Inc.

LABEL IN PART: (Vial and ctn.) "Dipyrone Injection 500 mg. per cc. Caution: Federal law prohibits * * * For intramuscular, intravenous or subcutaneous use * * * Each cc. contains: Dipyrone (methampyrone) 500 mg. * * * Distributed by Wolins Pharmacal Corp., Mineola, New York."

ACCOMPANYING LABELING: Inserts entitled "Dipyrone Injection."

LIBELED: 8–6–64, E. Dist. N.Y.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 9–28–64. Default—destruction.

8298. **Colspan cold capsules.** (F.D.C. No. 50411. S. No. 49–061 A.)

QUANTITY: 48 ctns. containing a total of approximately 37,950 cellophane strips of 10 capsules each, at Allegan, Mich.

SHIPPED: 5–25–64, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Ctn.) "Zenith Laboratories, Inc., Englewood, N.J. * * * 800 Colspan T.D. #1 Red & Clear Each T.D. Capsule Contains Belladonna Alkaloidal Salts, Total 0.16 mgm. Atropine Sulfate 0.024 mgm. Hyoscyamine Sulfate 0.122 mgm. Scopolamine Hydrobromide 0.014 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. * * * Dosage: 1 capsule in the morning and 1 capsule at bedtime Caution."

LIBELED: 7–27–64, W. Dist. Mich.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use since the labeling failed to state the purposes and conditions for which the drug was intended.

DISPOSITION: 9–8–64. Default—destruction.

8299. **Nerve Nutrient Dietary Food Supplement tablets.** (F.D.C. No. 50549. S. No. 51–829 A.)

QUANTITY: 7 ctns., each ctn. containing 12 60-tablet vials, at Lima, Ohio.

SHIPPED: On 9–12–63 and 4–10–64, from Hollywood, Fla., by Pharmex, Inc.

LABEL IN PART: (Vial and ctn.) "Nerve Nutrient Dietary Food Supplement For Nerves Manufactured for C. M. Hunter Drug Co. Lima, Ohio Adult Dose: * * * Each delayed action tablet contains—33,333 Units Thiamin Hydrochloride (Vit. B) in a specially prepared manner so that the medication is gradually released over an 8–10 hour period."

LIBELED: 8–21–64, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the name of the article, "Nerve Nutrient," and the label statements "For Nerves" and "Medication," were false and misleading, since the article was not adequate and effective as a medication or as a nerve nutrient; and 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from such requirement.

DISPOSITION: 9–24–64. Default—destruction.

8300. Sodium salicylate tablets. (F.D.C. No. 50415. S. Nos. 78–457/59 A.)

QUANTITY: 12 5,000-tablet ctns. at Farmingdale, N.Y.

SHIPPED: Between 4–24–64 and 5–11–64, from Philadelphia, Pa., by Dumont Pharmacal Co.

LABEL IN PART: (Ctn.) "Wolins Sodium Salicylate * * * Enteric Coated 10 gr. (0.65 gms.) * * * Distributed by Wolins Pharmacal Corp. Mineola, N.Y. Caution * * * Dosage: One tablet every 4 to 8 hours."

LIBELED: 8–27–64, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, "*Sodium Salicylate Tablets*," the name of which is recognized in the United States Pharamacopeia, an official compendium, and the quality of the enteric coating of the article fell below the standard set forth in such compendium; 502(a)—the label statement "Sodium Salicylate U.S.P. Enteric Coated" was false and misleading as applied to a product which failed to disintegrate in accordance with the requirements of the United States Pharmacopeia for enteric-coated tablets; and 502(f)(2)—the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as were necessary for the protection of users.

DISPOSITION: 9–28–64. Default—destruction.

8301. Sacro-Disc-30 tablets. (F.D.C. No. 49526. S. No. 4–997 X.)

QUANTITY: 33 btls., at Baltimore, Md., in possession of Armisyl Products, Inc.

SHIPPED: 8–26–63, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "100 Tablets New Improved Sacro-Disc-30 Thiamin Chloride 100 Mg. U.S.P. (Aneurine Hcl) Acetylsalicylic Acid (300 Mg. (Aspirin)) Dose * * * Distributed by Armisyl Products, Inc. * * * Baltimore 9, Md. Remember: If there is redness of joints or if your condition fails to respond in 10 days, or if there is fever, consult your physician so that he may properly diagnose your condition."

ACCOMPANYING LABELING: Leaflet entitled "Suffering? Backaches Sacroiliac Disc Pains Lumbago Sciatica Arthritis Rheumatism Polyneuritis Sacro-Disc 30 contains medication known to ease pains and discomfort for arthritic pains, rheumatism, and rheumatic pains, muscular aches, neuritis, bursitis and neuralgia * * *Armisyl Products Co."

RESULTS OF INVESTIGATION: The article was repacked by a firm in Baltimore, Md., and subsequently delivered to Armisyl Products, Inc. The leaflets were used by the dealer in promoting sales of the article.

LIBELED: 11–20–63, Dist. Md.

CHARGE: 502(a)—while held for sale, the name of the repack article, "*Sacro-Disc-30*," and statements in the labeling, namely, the repack-bottle label and

the leaflet described above, accompanying the article, made false and misleading representations and suggestions that the articles were adequate and effective for the treatment of ailments of the back, including the sacroiliac region, disc ailments, lumbago, sciatica, polyneuritis, neuritis, arthritis, rheumatism, and bursitis; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the treatment of the diseases and conditions for which the articles were intended, namely, ailments of the back, including the sacroiliac region, disc ailments, lumbago, sciatica, polyneuritis, neuritis, arthritis, rheumatism, and bursitis, since adequate directions cannot be written because these conditions are not amenable to self-diagnosis.

DISPOSITION: On 12–10–63, an answer was filed by the claimant, Armisyl Products, Inc., Baltimore, Md., denying that the article was misbranded. On 7–2–64, the Government served interrogatories on the claimant. On 10–27–64, a consent decree of condemnation was filed; thereafter, the article was destroyed.

8302. Nautrol pediatric suppositories. (F.D.C. No. 50251. S. No. 35–127 A.)

QUANTITY: 1,844 12-unit pkgs. at Chattanooga, Tenn.

SHIPPED: 11–7–63, from Jersey City, N. J., by G & W Laboratories.

LABEL IN PART: (Pkg.) "One Dozen Rectal Inserts Nautrol Pediatric Each Suppository Contains Pentobarbital Sodium 30 Mg. Warning—Pyrilamine Maleate 25 Mg.—Caution—See Insert—Mfg. For Provident Pharmaceuticals, Inc., Chattanooga, Tenn."

LIBELED: 7–10–64, E. Dist. Tenn.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use, and it was not exempt from that requirement, since the labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects and precautions under which practitioners can use the drug safely.

DISPOSITION: 9–17–64. Consent—claimed by Reid-Provident Laboratories, Inc., of Atlanta, Ga., for relabeling.

8303. Lindquist Chronosonic Ultrasound device, Auto-Electronic Radioclast devices, and Electronic Magnetic Model G devices. (F.D.C. No. 49220. S. Nos. 18–283 X, 18–284/8 X, 18–289/90 X.)

QUANTITY: 1 *Lindquist Chronosonic Ultrasound device*, 4 *Auto-Electronic Radioclast Model 20 devices*, 1 *Auto-Electronic Radioclast Model RR 20 device*, and 2 unlabeled *Electronic Magnetic Model G devices*, at Lancaster, Tex., in possession of John Alexander Hunt.

SHIPPED: Prior to 7–15–63, from Los Angeles, Calif., and Tiffin, Ohio.

LABEL IN PART: (Control panel) "Lindquist Chronosonic Ultrasound R. J. Lindquist Company * * * Los Angeles, California," "Auto-Electronic Radioclast Model 20 * * * Electronic Instrument Company, Tiffin, Ohio" and "Auto-Electronic Radioclast Mfd. by Electronic Instrument Co. Tiffin, Ohio Model RR 20."

ACCOMPANYING LABELING: Booklet reading in part "Electronic Magnetic Instrument Model G This instrument was custom built for J. A. Hunt, 210 N. Monroe St., Waxahatchie, Texas * * * by L. L. Roby Manufacturing Corp., Tiffin, Ohio" which accompanied the unlabeled device designated as "Electronic Magnetic Model G."

RESULTS OF INVESTIGATION: Inspection of the *Lindquist Chronosonic Ultrasound device* indicated that it was an electronic high-frequency oscillator circuit of the self-rectifying type, having a pulsed power output and a soundhead applicator which generated the ultrasound energy. The circuit was enclosed in a simulated leather case with storage space for the electrical wires and soundhead. The gray "hammertone" panel contained a milliampere meter, internal timer with automatic shutoff, tuning control, and a 10-position power control. The soundhead was connected to the instrument circuit through a flexible coaxial cable.

Information concerning the *Auto-Electronic Radioclast Model 20* and *Auto-Electronic Radioclast Model RR 20*, showed that each of the devices was a wood cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of three dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present, and additional dials determined the intensity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determine the location of the disease in the body.

The *Electronic Magnetic Model G device* was a suitcase-type unit which, on opening, revealed the control panel and storage, power, and magnetic control switches and an electronic control dial. The two electronic electrodes were rectangular metal strips and the magnetic electrodes were two coils of wire enclosed in a metal housing approximately 6 inches in diameter. The electronic electrodes applied 7.2-cycles-per-second current to the body, and the magnetic coils operated on 220 cycles per second.

LIBELED: On or about 8–6–63, N. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article, *Lindquist Chronosonic Ultrasound*, failed to bear adequate directions for use and it was not exempt from such requirement, since it was a prescription device and it was not in the possession of a practitioner licensed by law to use or order the use of such device as required by regulations; and 502(f)(1)—the labeling of the articles, *Auto-Electronic Radioclast Model 20*, *Auto-Electronic Radioclast Model RR 20*, and *Electronic Magnetic Model G*, failed to bear adequate directions for use in the diagnosis or treatment of any disease conditions, and it was not feasible to devise any directions for use because the articles were worthless for any medical purposes.

DISPOSITION: 5–27–64. Default—destruction.

8304. Dr. Scholl's devices. (F.D.C. No. 50688. S. Nos. 45–940/4 A.)

QUANTITY: 6 *Pedasine devices*, 1 *Medco-sonlator device*, 150 ctns., each containing 1 pair of shoes, and 5 single unit and 11 double unit individually ctnd. *Electric Foot Massager devices*, at Denver, Colo., in possession of Dr. Scholl Foot Comfort Shop.

SHIPPED: Between unknown date prior to 1–1–56 and 9–10–64, from California, Oklahoma, Ohio, and Illinois.

LABEL IN PART: (Device) "Pedasine * * * Continuous Interrupted Volts * * * Legs Arches"; "Medco-sonlater * * * Caution to be used only by or on the pretion of a physician"; (box) "Dr. Scholl's Foot Comfort Shoes"; and (ctn.) "Dr. Scholl's Electric Foot Massager Feet Rest Normally on Exclusive 30 Degree Angle."

ACCOMPANYING LABELING: Leaflet in carton entitled "how to use Dr. Scholl's Electric Foot Massager"; placards reading in part "Don't Let Foot Troubles Affect Your Earning Power"; booklets entitled "Treatment and Care of the Feet By Dr. Wm. M. Scholl"; and placards entitled "Here under one roof . . . Everything for the relief of All Common Foot Troubles" and "Nervousness, Droop Shoulder, Body Fatigue, Backache, Rheumatic like Pains."

RESULTS OF INVESTIGATION: Examination showed that the *Pedasine device* was an electrical device contained in a dispatch-type carrying case with four metal plate electrodes, switches, intensity control knob, timer and external pad electrodes, and that, in use, it was a synchronous motor-controlled sinusoidal current generator.

The *Medco-sonlator device* was an electrical device incorporating in one cabinet, both a muscle-stimulator unit and an ultrasonic generator, with a three-way head, watt meter, time control knob, pilot light, and knob for controlling ultrasound intensity. In use, the device was plugged into an electrical outlet and the ultrasonic portion of the device operated with an ultrasound frequency of one megacycle. A three-way sound and stimulator switch controlled the head which may be used in three ways: (1) as a conventional soundhead applicator; (2) as a movable, electric muscle stimulator; and (3) simultaneously, as a conventional soundhead applicator and movable, electric muscle-stimulator electrode.

Dr. Scholl's Foot Comfort Shoes consisted of black leather lace-type shoes with a composition sole and a built-up wooden heel with rubber cushion.

Dr. Scholl's Electric Foot Massager device consisted of an electrical vibrating device in the form of a small footrest housed in a plastic case. The device was sold in two models, one having one vibrating head and one having two vibrating heads.

LIBELED: 10–28–64, Dist. Colo.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective for the treatment of all common foot troubles, nervousness, backache, foot and leg pains, varicose veins, droop shoulder, body fatigue, painful heel, pain in knee, tender heel, pain in hips, flat foot, weak or fallen arches, neuritis, sciatica, cramped toes, weak ankles, stiff and clumsy feet, excessive perspiration, swollen feet, sudden cramp-like pains, enlarged toe joints, distress all over the body, and that use of the articles would straighten crooked or overlapping toes and hammer toes, straighten the muscles and strengthen and invigorate the feet; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for broken down metatarsal arch, leg trouble, weak foot, swollen muscles, varicose veins, hurting in the back, legs, and hips, back pain, and to exercise the circulation, stimulate the legs, lift the arches, shove the muscles up, shorten the muscles, and break down calcium formation in the joints, which were the conditions and purposes for which the articles were offered in oral statements made by salesmen for the dealer firm, Dr. Scholl Foot Comfort Shop, on 7–24–64.

DISPOSITION: 12–30–64. Default—135 pairs of shoes delivered to a government institution; other devices and promotional material delivered to the Food and Drug Administration.

8305. Hydrotherapy device. (F.D.C. No. 50867. S. No. 30–370 A.)

QUANTITY: 3 devices at Nashville, Tenn., in possession of Southern Hi-Dro Whirlpool Co.

SHIPPED: Between 6–24–64 and 10–19–64, from St. Louis, Mo., by Hi-Dro Whirlpool Bath Co.

LABEL IN PART: (Device front) "Hi-Dro Company Whirlpool Hydro Massage" and (device back) "Hi-Dro Company, St. Louis, Missouri * * * Model * * * Serial * * * Whirlpool Hydro Massage."

ACCOMPANYING LABELING: Booklets entitled "Pain and the Relief of it"; newspaper reprints entitled "To Your Good Health"; cards entitled "Do You Suffer From"; leaflets entitled "Pain and the relief of it"; pamphlets entitled "Quackery in Arthritis"; magazine reprints entitled "The Cruelest Swindle in Medical 'Cures'"; and copies of a letter signed "Mrs. Ruby Robinson."

RESULT OF INVESTIGATION: The device consisted of a 1-horsepower electric motor housed in a portable plastic carrying case with automatic timer and on/off switch. A flexible hose attached the device to an adjustable activator ring intended to be placed in the bathtub, which ring contained 60 holes for emitting preheated jets of air into the water of the bath.

The booklets and newspaper reprints were received from the shipper; the other pieces of accompanying labeling were obtained from local sources or prepared by the dealer for the purpose of promoting sales of the device.

LIBELED: 12–9–64, M. Dist. Tenn.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and cure of diseases, including arthritis, abscesses, infections, arteriosclerosis of the feet, adherent scars, bromidrosis, bursitis, chilblains, contusions, hyperephidrosis, Heberden's nodes, indolent ulcers, many forms of peripheral vascular disease, osteomyelitis of terminal phalanges, pain and muscular spasm, postcare of fractures, peripheral nerve injuries, painful stumps, poor circulation, Raynaud's disease, rheumatism, sprains, strains, scleroderma, tender and sensitive feet, and thromboangiitis obliterans; and that use of the article traumatized nerves, joints and muscles; broke down all hardened inflammatory deposits; relaxed muscular structures; loosened joints; softened ligaments; increased venous activity and the return of the blood to the general body circulation; and had a most pronounced action upon the nervous system; restored circulatory function in limbs actually darkened by stagnation; increased the size of the limbs; that defects were modified and eventually removed if they were capable of any relief; that the article would improve posture; firm sagging muscles; take off inches in any program of weight control; and that the article was one of the most powerful of the physical curative measures in hydrology for those lesions involving the areas that can be treated; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in the treatment of heart disease, heart trouble, muscular diseases, vascular disease, muscular dystrophy, back trouble, rheumatoid arthritis, and arthritis of the spine and hips, which were the conditions for which the article was recommended in oral satements made on 10–21–64, at the Southern Hi-Dro Whirlpool Co., Nashville, Tenn., by the firm's salesman, Jerry Feldman.

DISPOSITION: 1–6–65. Default—the devices were ordered delivered to charitable institutions; the accompanying labeling was ordered destroyed.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICE FOR HUMAN USE*

8306. **Cysan-C.** (F.D.C. No. 50699. S. No. 55–878 A.)

QUANTITY: 4 ctns. containing a total of 290 vials at Kansas City, Mo.

SHIPPED: 5–11–62, from Chicago, Ill.

LABEL IN PART: (Ctn.) "Private Formula Quantity 100 Labeled: Cysan-C 10 cc. Size Intramuscular Multiple Dose Liver-Folic Acid–B-12 Each cc. contains Vitamin B-12 activity (from Liver Inj. U.S.P. Beef) equivalent to: Cyanocobalamin 10 mcg. Fortified with Folic Acid 0.4 mg., Vitamin B-12 100 mcg."

ACCOMPANYING LABELINGS: (Label to be fixed to vials) "Cysan-C 10 cc. Each cc. contains: Liver Inj. N.F. * * * B_{12} 10 mcgm. Cyanocobalamin added 100 mcgm. Folic Acid 0.4 mg. * * * Mfg. for Marion Laboratories, Inc. Kansas City, Mo. 5225."

RESULTS OF INVESTIGATION: Analysis shows that the article contained approximately 25 percent of the declared amount of the folic acid, and approximately 75 percent of the declared amount of vitamin B_{12}. The above-mentioned vials were to be labeled by Marion Laboratories, Inc., with the vial labels described above.

LIBELED: 11–6–64, W. Dist. Mo.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statements (carton) "Each cc. contains * * * Cyanocobalamin 10 mcg. * * * Folic Acid 0.4 mg., Vitamin B-12 100 mcg." and (vial) "Each cc. contains: * * * B-12 10 mcgm. Cyanocobalamin added 100 mcgm. Folic Acid 0.4 mg." were false and misleading as applied to a product containing less than the declared amounts of these ingredients.

DISPOSITION: 1–13–65. Default—destruction.

8307. **Desoxyephedrine hydrochloride capsules.** (F.D.C. No. 50828. S. No. 27–292 A.)

QUANTITY: 1 25,000-capsule drum at Chicago, Ill.

SHIPPED: 3–13–63, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 79.1 percent of the declared amount of desoxyephedrine hydrochloride.

LIBELED: 11–27–64, N. Dist. Ill.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Each capsule contains: D-Desoxyephedrine HCl 20 mg.," was false and misleading as applied to a product containing less than the declared amount of this ingredient.

DISPOSITION: 1–12–65. Default—destruction.

8308. **Digoxin tablets.** (F.D.C. No. 50160. S. No. 7–456 A.)

QUANTITY: 47 1,000-tablet btls. at Baltimore, Md.

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*See also No. 8300.

SHIPPED: 3–18–64, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Btl.) "National * * * Digoxin 0.25 mg. The National Pharmaceutical Mfg. Co. Baltimore, Md. * * * Caution: * * * Average dose."

RESULTS OF INVESTIGATION: Analysis showed that the article varied, in individual tablet-potency, materially more or less from the potency declared on the label.

LIBELED: 5–26–64, Dist. Md.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Digoxin 0.25 mg." was false and misleading.

DISPOSITION: 1–8–65. Default—destruction.

8309. Teebacin tablets. (F.D.C. No. 50854. S. No. 41–221 A.)

QUANTITY: 28 btls. at Galveston, Tex.

SHIPPED: 10–23–64, from Katonah, N.Y., by Consolidated Midland Corp.

LABEL IN PART: (Btl.) "CMC Research Division 1000 Teebacin Tablets Captabs Each tablet contains 1.0 Gram Sodium Para Amino Salicylate Caution: Federal law prohibits * * * Distributed by A Division of Consolidated Midland Corporation Katonah, New York * * * Powder Mfg. 6–8–64 Tablets Mfg. 7–22–64."

RESULTS OF INVESTIGATION: Analysis showed that sodium salicylate tablets had been in part substituted for sodium para-aminosalicylate tablets.

LIBELED: 12–4–64, S. Dist. Tex.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, Sodium Aminosalicylate Tablets, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from and its quality or purity fell below, the standard set forth in such compendium; 501(d)(2)—sodium salicylate tablets had been substituted in part for sodium para-aminosalicylate tablets, which the article was represented to be; and 502(a)—the label statement "Each tablet contains 1.0 Gram Sodium Para Amino Salicylate" was false and misleading as applied to a product consisting in part of sodium salicylate.

DISPOSITION: 1–5–65. Default—delivered to the Food and Drug Administration.

8310. Nitroglycerin tablets. (F.D.C. No. 50521. S. No. 20–811 A.)

QUANTITY: 113 1,000-tablet btls. and 12 100-tablet btls., at Oakmont, Pa., in possession of The Zemmer Co., Inc.

SHIPPED: 7–17–63, from Wilmington, Del.

LABEL IN PART: (Btl.) "Nitroglycerin 0.6 Mg. The Zemmer Co. Pittsburgh, Pa., Each Tablet Represents Nitroglycerin 0.6 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 118 percent of the declared amount of nitroglycerin which was in excess of the limits set forth in the United States Pharmacopeia. The article was manufactured by the dealer from bulk powder shipped as above.

LIBELED: 9–14–64, W. Dist. Pa.

CHARGE: 501(b)—while held for sale, the article purported to be a drug, the name of which was recognized in an official compendium, and its strength differed from that which it was purported to possess; and 502(a)—the label

statement "Nitroglycerin 0.6 Mg. * * * Each Tablet Represents Nitroglycerin 0.6 Mg." was false and misleading.

DISPOSITION: 10–26–64. Default—delivered to a public institution.

8311. **Meperidine hydrochloride injection.** (F.D.C. No. 50876. S. No. 64–878 A.)

QUANTITY: 14 ctns., each containing 2 cellophane-wrapped trays of 5 1–cc. Tubex units each, at Lancaster, Calif.

SHIPPED: 1–8–63, from West Chester, Pa., by Wyeth Laboratories, Inc.

LABEL IN PART: (Ctn.) "Ten Tubex Sterile Cartridge-Needle Units (1 cc. size) Tubex Injection Meperidine Hydrochloride—Each Tubex cartridge contains 100 mg. Meperidine Hydrochloride Warning—Caution—Wyeth Laboratories, Inc. Philadelphia, Pa.—Each unit includes one sterile Tubex hypodermic needle (22 gauge, 1–¼ inch)"; and (Tubex unit) "Meperidine Hydrochloride 100 [or "50"] mg. per cc.—Wyeth Phila."

RESULTS OF INVESTIGATION: Each Tubex unit contained 100 mg. of meperidine hydrochloride, but some units bore incorrect labels reading "50 mg."

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Meperidine Hydrochloride 50 mg. per cc." was false and misleading as applied to a product containing 100 milligrams of meperidine hydrochloride per cubic centimeter.

DISPOSITION: 12–31–64. Default—destruction.

8312. **Surgical drainage bottles.** (F.D.C. No. 49637. S. No. 40–029 X.)

QUANTITY: 410 cases, each containing 4 btls., at Lodi, N.J.

SHIPPED: 7–11–63, from Alton, Ill.

LABEL IN PART: (Btl.) "3000 cc * * * 700 cc Melco * * * Medical Equipment Division Melchior, Armstrong, Dessau, Inc. Ridgefield, New Jersey"; and "3000 cc * * * 700 cc Linde * * * Linde Company Division of Union Carbide Corporation."

RESULTS OF INVESTIGATION: The articles had been shipped as above, as unmarked glass gallon jars. Ceragraphic, Inc., Hackensack, N.J., had applied the measuring scale and the brand names to the bottles and had shipped them to Lodi, N.J.

LIBELED: 12–16–63, Dist. N.J.

CHARGE: 501(c)—while held for sale, the quality of the articles fell below that which they were purported to possess; and 502(a)—the labeling of the articles, namely, the measuring scale inscribed on the bottles, was false and misleading since such measuring scale was inaccurate.

DISPOSITION: 4–21–64. Default—destruction.

DRUGS FOR VETERINARY USE

8313. **Min-A-Sul veterinary preparation.** (F.D.C. No. 48171. S. Nos. 34–976 T, 58–645 T.)

INFORMATION FILED: 4–30–63, Dist. Minn., against Herbert A. Gilbertson, t/a Valley Vet Supply, Kenyon, Minn.

ALLEGED VIOLATIONS: During the period from 3–30–62 to 4–6–62, and while quantities of a mineral compound were being held for sale after shipment in inter-

state commerce, the defendant caused the compound to be mixed with articles represented to contain sulfamethazine, sulfanilamide and sulfathiazole, and caused the finished product, *Min-A-Sul*, to be packed as a drug in jars labeled as described below, which acts of the defendant resulted in the *Min-A-Sul* being adulterated and misbranded. The defendant also caused quantities of the *Min-A-Sul* to be shipped in interstate commerce, between 3–21–62 and 4–4–62, into the State of Iowa.

LABEL IN PART: (Jar) "Min-A-Sul Combination Sulphas with Mineral For Aid in the Treatment of Mastitis Active Ingredients—100% Sulphamethazine, Sulphanilamide, Sulphathiazole, Ammonium Sulphate, Potassium Iodide, Copper Sulphate, Iron Sulphate, Iron Oxide, Niacin, Licorice Root, Anise. Distributed by Valley Vet Supply, Willmar, Minnesota."

ACCOMPANYING LABELING: Leaflets entitled "Min-A-Sul for Mastitis and Infected Udders."

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess in that it purported and was represented to contain significant amounts of sulfamethazine, sulfanilamide, and sulfathiazole, whereas the article contained insignificant amounts, if any, of sulfamethazine, sulfanilamide, and sulfathiazole; and 502(a)—while held for sale, the label statement "Active Ingredients * * * Sulphamethazine, Sulphanilamide, Sulphathiazole" was false and misleading; and 502(a)—the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for overcoming mastitis and infected udders in cows, swollen and infected udders in sows and sheep, and for overcoming intestinal diseases in swine.

PLEA: Guilty.

DISPOSITION: On 2–14–64, the defendant was placed on probation for 2 years. On 10–30–64, a hearing was held at which the defendant pleaded guilty to eight violations of probation. The court thereupon revoked the defendant's probation and sentenced the defendant to 3 years' imprisonment.

8314. Purina Medicated Pig Startena (Special) feed. (F.D.C. No. 49821. S. Nos. 55–702 X, 32–921 A.)

QUANTITY: 25 100-lb. bags at Oxford, Ohio.

SHIPPED: 10–1–63 and 10–3–63, from Richmond, Ind., to Ralston Purina Co.

LABEL IN PART: (Tag) "Purina Medicated Pig Startena (Special)—Active Drug Ingredients:—Furazolidone 0.011 percent Ralston Purina Co., Gen. Offices, St. Louis, Mo. Guaranteed Analysis—Ingredients—Directions For Use Feed As Sole Creep Ration Whenever Scours Is A Persistent Problem. Discontinue 5 Days Before Marketing."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 64 percent of the declared amount of furazolidone.

LIBELED: 3–5–64, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Furazolidone 0.011 percent" was false and misleading as applied to a product containing less than the declared amount of furazolidone.

DISPOSITION: On 4–30–64, the claimant, Ralston Purina Co., filed an answer. On 2–17–65, a consent decree of condemation and destruction was filed which read in part that the claimant, while not admitting the allegations of the libel, believed that no useful purpose would be served by contesting the case, and thus was willing to consent, the article having deteriorated since the commencement of the action.

8315. **Medicated feed.** (F.D.C. No. 50560. S. No. 54–666 A.)

QUANTITY: 63 50-lb. bags, at Dysart, Iowa, in possession of Evergreen Hatchery & Elevator.

SHIPPED: The article was prepared in part from diethylstilbestrol shipped on 11–7–63, from Lafayette, Ind.

LABEL IN PART: (Tag) "100 Lbs. Net Evergreen 0.0022 percent Diethylstilbestrol Mixture for Fattening Beef Cattle. Feed at the rate of 1 pound per animal per day. Each pound contains 10 milligrams diethylstilbestrol * * * Manufactured by Evergreen Hatchery, Inc., Dysart, Iowa."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of diethylstilbestrol.

LIBELED: 9–3–64, N. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statements "Diethylstilbestrol 0.0022 percent" and "For Fattening Beef Cattle," were false and misleading.

DISPOSITION: 9–29–64. Consent—claimed by Evergreen Hatchery, Inc., and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

8316. **Unitrol capsules.** (F.D.C. No. 43464. S. No. 80–027 P.)

QUANTITY: 60 28-capsule btls. and 48 7-capsule btls., at Detroit, Mich.

SHIPPED: On 7–8–59 and 8–29–59, from Buffalo, N.Y., by Republic Drug Co., Inc.

LABEL IN PART: "Unitrol A True Appetite Depressant One Capsule Works All Day, Republic Drug Company, Buffalo, New York * * * Each Capsule Contains: Phenyl Propanolamine Hydrochloride 75 Mg. In a Special Base that Provides for Timed Disintegration of the Contents Over a Period of Approx. 6 to 10 hours. This Capsule is Equal to One Tablet of 25 Mg. Potency Taken 3 Times Daily."

ACCOMPANYING LABELING: A counter display carton reading in part "Safe Easy Reducing Plan," and window banners reading in part "Lose Weight Unitrol * * * That's all" and "Lose Weight up to 14 Lbs. in 14 days Unitrol That's all" which were received from Republic Drug Co., Inc.

LIBELED: 9–30–59, E. Dist. Mich.; libel amended 2–14–62.

CHARGE: 502(a)—when shipped and while held for sale, the statements in the labeling of the article, namely, the bottle label, the insert leaflet, the counter display cartons, display cards and window banners, represented and suggested

*See also Nos. 8281, 8282, 8291–8293, 8295, 8296, 8299–8301, 8304–8312.

that the article was an adequate and effective treatment for obesity, and was effective as an appetite depressant, in that the article would cause one to lose weight without rigid diets, by the use of such statements, among others, as "A True Appetite Depressant," "ONE CAPSULE WORKS ALL DAY," "LOSE WEIGHT—Look and Feel Lovely * * * Unitrol A True Appetite Depressant, Guaranteed Effective," "ONE CAPSULE WORKS ALL DAY—If You Want to Lose Weight * * * Curb Your Appetite the Safe Easy Unitrol Way—Guaranteed Effective," "LOSE WEIGHT UP to 14 LBS. IN 14 DAYS THAT'S ALL—UNITROL—1 CAPSULE WORKS ALL DAY" which representations, suggestions, and statements were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: On 11–4–59, pursuant to stipulation between the Government and the claimant, Republic Drug Co., Inc., Buffalo, N.Y., the court ordered the case transferred to the United States District Court for the Western District of New York. On 12–29–59, Republic Drug Co., Inc., filed an answer denying that the article was misbranded. On 10–31–60, the Government served written interrogatories upon the claimant. On 11–8–60, the claimant filed answers to the Government's written interrogatories. Subsequently, Nysco Laboratories, Inc., Long Island City, N.Y., was substituted as claimant for the original claimant, Republic Drug Co., Inc. On 12–28–60, pursuant to stipulation between the parties, the court ordered the transfer of the case to the United States District Court for the District of New Jersey. On 2–9–62, the Government filed a motion to amend libel which motion was granted on 2–14–62. On 4–9–62, the Government served additional written interrogatories which were subsequently answered by the claimant. On 5–9–62, the case came on for trial without a jury. After 5 days of trial the court took the case under advisement.

On 9–27–62, the court handed down an opinion (211 F. Supp. 207) in which it concluded upon the basis of the evidence presented that a daily dosage level of 75 mg. of PPA (phenylpropanolamine hydrochloride) had no significant pharmacological value as a weight-reducing agent; and that any representation to the effect that PPA in such dosage was adequate and effective as an appetite depressant or was adequate and effective in the management or control of obesity would be a misbranding. The court found that the labeling of the article represented that its sole active ingredient, PPA, was adequate and effective for the above purposes and consequently that the article was to be condemned.

Pursuant to the court's opinion, a decree of condemnation and destruction was entered on 1–22–63. Thereafter, the case was appealed by the claimant to the United States Court of Appeals for the Third Circuit and, on 12–3–63, the court rendered the following opinion (325 F. 2d 513):

PER CURIAM: "This is an appeal from a judgment of the district court condemning certain articles of drug as misbranded within the meaning of 21 U.S.C. § 352(a) (1958 ed.). The appellant contends that the district court erred in holding that the burden of proof on the United States in a misbranding action requires only that it prove its contention by a fair preponderance of the evidence. It is asserted that our decision in *Van Camp Sea Food Co.* v. *United States*, 82 F. 2d 365 (C.A. 3. 1936), rejects that standard in cases of this type and requires a higher degree of proof on the part of the government, i.e., that it establish its case by clear and satisfactory evidence.

"There is language in *Van Camp* which purports to adopt the rule urged by the appellant. However, it appears from an analysis of the opinion in that case that this language was not decisional, for the court premised its dismissal of the libel on the following supposition:

'But assuming for present purposes the instructions of the court were right and that in a forfeiture case the preponderance, as in a civil case, is all that is required, did the proofs make out such a case that it could be submitted by [sic] a jury to find there was a preponderance? The answer to this question requires the critical study of the proofs, which we now try to make.' 82 F. 2d at 366.

Thus the court's expression of agreement with the 'clear and satisfactory evidence' test was not essential to its decision. Moreover, the holding in *Van Camp* was based on a construction of the Food and Drugs Act of 1906, whereas the instant action was brought under the Federal Food, Drug, and Cosmetics Act of 1938, 21 U.S.C. §§ 301, 392 (1958 ed.). The appellate cases considering the question under the 1938 Act adopt the fair preponderance of the evidence criterion. *United States* v. *Wood*, 226 F. 2d 924 (C.A. 4, 1955); *United States* v. *449 Cases, Containing Tomato Paste*, 212 F. 2d 567, 573 (C.A. 2, 1954); *United States* v. *5 Cases more or less Containing 'Figlia Mia Brand,'* 179 F. 2d 519, 524 (C.A. 2), cert. denied, 339 U.S. 963 (1950). See also, *C.C.Co.* v. *United States*, 147 F. 2d 820, 824 (C.A. 5, 1944). Because of the public interest in cases of this kind, we think that the rationale of these decisions is unassailable. Accordingly, we hold that the district court applied the proper evidentiary standard to the case at bar.

"The appellant also makes a broad frontal attack on the findings of the district court, asserting that they are clearly erroneous. However, an examination of the record convinces us that there is a plethora of evidence both documentary and testimonial to support the district court's factual determinations.

"The appellant has also filed a motion to remand this case to the district court on the basis of newly discovered evidence, but the evidence cited to support the motion is not of sufficient character as would justify the granting of such relief.

"The judgment of the district court will be affirmed, and the motion to remand will be denied."

8317. **Super-Dreen capsules.** (F.D.C. No. 43454. S. No. 78–895 P.)

QUANTITY: 143 14-capsule btls., at Detroit, Mich., in possession of Warren Pharmacy.

SHIPPED: 8–5–59, from Chicago, Ill., by Super Products (Super Nature Corp.).

LABEL IN PART: (Btl.) "Super-Dreen An Appetite Depressant for Use in the Dietary Control of Obesity. Each Time Cap Contains Phenylpropanolamine Hydrochloride 50 Mg. Distributed by Super Products * * * Chicago, Ill.," and (display and shipping ctn.) "Fat Melts Away * * * Super-Dreen—Reduces the Appetite * * * Just released for sale without prescription * * * 343."

ACCOMPANYING LABELING: Insert leaflets entitled "Dear Reducer, Super-Dreen Time Capsules Act As An Appetite Reducant," and printed signs reading in part, "Lose Up to 14 Pounds in 14 Days," "Take the Amazing New Reducer Lose Ugly Fat Easily," "Just Released for Sale without Prescription. Super-Dreen," and "More than 25,000 Caps One a Day Capsules Used Effectively to Help People Reduce."

RESULTS OF INVESTIGATION: The signs listed above had been printed locally and had been used in conjunction with the dealer's displays of the article.

LIBELED: 9–28–59, E. Dist. Mich.; libel amended on or about 2–9–62.

CHARGE: 502(a)—when shipped and while held for sale, the statements in the labeling of the article, namely, the bottle label, the insert leaflet in the bottles, the counter display and shipping carton, signs on the counter above the display carton, a sign on the post in front of the counter, and signs appearing on a post on the premises, represented and suggested that the article was effective as an appetite depressant in the control of obesity; which

representations and suggestions were misleading since the article was not adequate and effective for such purposes.

DISPOSITION: On 11–27–59, Super Nature Corp., Chicago, Ill., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described bottle label, display and shipping carton, leaflets and posters. On 11–24–60, the Government served written interrogatories upon the claimant. The claimant filed an answer to the Government's written interrogatories on or about 12–13–60. Also, on the same date, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey, and an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., was substituted as the claimant. On or about 2–9–62, the Government filed an amended libel.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8318. Offat capsules. (F.D.C. No. 44711. S. No. 4–505 R.)

QUANTITY: 62 30-capsule vials and 62 15-capsule vials, at Baltimore, Md., in possession of Barre Drug Co., Inc.

SHIPPED: On 5–11–60, from Long Island City, N.Y.

LABEL IN PART: "Offat—Each capsule contains 75 mgm. Phenyl Propanolamine Hydrochloride in a special timed disintegration base that provides for prolonged therapeutic effect for about 6 to 10 hours. Indications for Use: Offat capsules aid in weight reduction and control by curbing the appetite, thereby making it easier to adhere to a low caloric diet. Caution: * * * Distributed by Rojel Company, Baltimore, Maryland Division The Barre Drug Co."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked the article from a bulk shipment, into 30-capsule vials and 15-capsule vials.

LIBELED: 7–7–60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name "*Offat*" represented and suggested that the article was capable of causing the user to lose fat; and in that statements in the labeling, namely, the vial label described above, represented and suggested that the article was adequate and effective for weight reduction and control by curbing the appetite; which name and statements were false and misleading, since the article was not adequate and effective for such purposes.

DISPOSITION: On 8–15–60, the Barre Drug Co., Inc., Baltimore, Md., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described vial label. On or about 11–22–60, the Government filed written interrogatories which were answered by the claimant on 12–16–60. Also, on the same date, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey, and an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8319. **Weydex capsules.** (F.D.C. No. 43576. S. No. 59–550 P.)

QUANTITY: 108 display-type ctns., each containing 6 21-capsule btls., at Washington, D.C., in possession of Jason Pharmacal Co.

SHIPPED: 6–9–59, from Long Island City, N.Y.

LABEL IN PART: (Ctn.) "Lose Weight Fast! * * * Weydex Time Released Capsules * * * Jason Pharmacal Co., Washington, D.C.," and (btl.) "WEYDEX Timed Disintegration Capsules Dose One Capsule a Day * * * Each capsule contains 75 mgm. Phenylpropanolamine Hydrochloride in a special timed disintegration base that provides for prolonged therapeutic effect for about 6 to 10 hours. * * * Dist. by Jason Pharmacal Co. Wash. D.C. 43262."

ACCOMPANYING LABELING: Booklet entitled "It's Fun to Lose Weight the Weydex Way."

LIBELED: 10–2–59, Dist. Columbia.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the bottle label, the display carton label, and booklet described above, contained statements which represented and suggested that the article was adequate and effective in curbing the appetite, causing one to lose weight fast; and that it was adequate and effective for weight control; which statements were false and misleading, since the article was not adequate and effective for such purposes.

DISPOSITION: On 10–21–59, Alvin Epstein, t/a Jason Pharmacal Co., Washington, D.C., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described bottle label, display carton label, and booklet. On or about 10–19–60, the Government filed written interrogatories. On 11–4–60, the court granted the claimant's motion for removal of the cause to the United States District Court for the District of New Jersey. Also, on the same date, Nysco Laboratories, Inc., Long Island City, N.Y., was substituted as the party claimant by order of the court. On 11–10–60, the claimant filed its answers to the Government's written interrogatories.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8320. **Nyscaps capsules.** (F.D.C. No. 43467. S. No. 29–420 P.)

QUANTITY: Approximately 25,000 capsules in a bulk drum, at Dallas, Tex., in possession of Preston-National Drug Co., Inc.

SHIPPED: On 10–9–59, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: "Nysco Laboratories, Inc. * * * Lot No. 45536 Nyscaps Timed Disintegration Capsules Phenyl Propanolamine Hydrochloride 75 mgm. * * * Aids in Weight Reduction and Control by Curbing the Appetite."

RESULTS OF INVESTIGATION: The bulk stock was intended to be repackaged by the dealer as an aid for reducing.

LIBELED: 10–21–59, N. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, statements in the labeling of the article, namely, the bulk drum label described above, represented and suggested that the article was effective in controlling the appetite in the management of obesity, which statements were false and misleading because the article was not effective for such purpose.

DISPOSITION: On 11–16–59, Preston-National Drug Co., Inc., Dallas, Tex., filed a claim to the article, and subsequently filed an answer denying that the article was misbranded by the above-described bulk drum label. On 11–4–60, the Government served written interrogatories upon the claimant. On 11–22–60, the claimant filed its answer to the Government's written interrogatories. Thereafter, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey. Also, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8321. **Trim'N Slim capsules.** (F.D.C. No. 44567. S. No. 6–473 R.)

QUANTITY: 54 ctns., each containing 12 boxes and 1 display poster, at Boston, Mass.

SHIPPED: On 2–4–60, from Brooklyn, N.Y., by Success Chemical Co., Inc.

LABEL IN PART: (Ctn.) "Slenderize One Capsule Daily Curb Your Appetite with New Trim'N Slim * * * 1 Dozen Packages," and (box) "21 Time Disintegration Capsules Trim'N Slim * * * Each Capsule Contains: Phenyl Propanolamine HCl 75 mg. * * * Appetite Suppression * * * Prepared for Berkeley Drug Co. Boston, Mass."

ACCOMPANYING LABELING: Leaflets entitled "Suggested Dietary Regimen," and display posters entitled "Slenderize One Capsule Daily."

LIBELED: 5–13–60, Dist. Mass.

CHARGE: 502(a)—when shipped, the name "*Trim'N Slim*" represented and suggested that the article was capable of making the user become slim; and statements in its labeling, namely, the box label, the insert leaflet, and a display poster, represented and suggested that the article was capable of effectively curbing the appetite; was useful as an appetite depressant in the dietary control of obesity; and that it would cause the user to lose weight by curbing and

suppressing the appetite; which name and statements were false and misleading since they were contrary to fact.

DISPOSITION: On 5–26–60, Success Chemical Co., Inc., Brooklyn, N.Y., filed a claim to the article, and on 6–30–60, it filed an answer denying that the article was misbranded by the above-described box label, insert leaflet, and display poster. On 7–8–60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey. Also, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant. On 11–17–60, the Government served written interrogatories upon the claimant; thereafter, the claimant filed its answer to the Government's written interrogatories. On 9–18–61, the claimant served written interrogatories upon the Government; thereafter, the Government filed an answer to the claimant's written interrogatories.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8322. **Sleek capsules.** (F.D.C. No. 43578. S. No. 59–555 P.)

QUANTITY: Approximately 395 21-capsule btls., at Washington, D.C., in possession of Mistretta & Co., Inc.

SHIPPED: On 5–15–59 and 6–15–59, from Long Island City, N.Y.

LABEL IN PART: "Sleek Dose: 1 Capsule a Day * * * Timed Disintegration Capsules Phenyl Propanolamine Hydrochloride 75 mgm. * * * Mistretta & Co., Inc., Distributor, Washington 7, D.C."

ACCOMPANYING LABELING: Order blanks reading in part "Sleek Dose: 1 Capsule a Day 21 Timed Disintegration Capsules," and booklets entitled "The Sleek Weight-Control Plan Makes it Fun to be . . . Slim Slender Sleek."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked the article into individually cartoned bottles from bulk lots shipped as described above.

LIBELED: 10–2–59, Dist. Columbia.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the bottle label, the order blank, and booklet enclosed in each carton, represented and suggested that the article was an adequate and effective treatment for obesity; which statements were false and misleading since the article was not an adequate and effective treatment for such purpose.

DISPOSITION: On 10–21–59, Mistretta & Co., Inc., Washington, D.C., filed a claim to the article, and thereafter, filed an answer denying that the article was misbranded by the above-described bottle label, order blank or booklet. On or about 10–19–60, the Government filed written interrogatories. On 11–4–60, the court granted the claimant's motion for removal of the cause to the United States District Court for the District of New Jersey; also, on the same date, Nysco Laboratories, Inc., Long Island City, N.Y., was substituted as the party claimant by order of the court. On 11–10–60, the claimant filed its answers to the Government's written interrogatories.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of*

America v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8323. Ajem's Formula 12 capsules. (F.D.C. No. 44226. S. No. 48–700 P.)

QUANTITY: 1 drum and 36 18-capsule boxes, at Oakland, Calif., in possession of Ajem Drug Co.

SHIPPED: On 9–21–59, from Long Island City, N.Y.

LABEL IN PART: (Box) "Ajem's Formula 12 Capsules Trim-down The Appetite Depressant–Delayed Action * * * Sole Distributors Ajem Drug Company 508 55th Street, Oakland, California The Scientific Weight Control (Each Capsule Contains: Phenylpropanolamine Hcl 75 Mg.)."

ACCOMPANYING LABELING: Cards, 30" x 40", entitled "Change from Weight Gaining"; display cards, 10" x 18", entitled "Change from Weight Gaining"; 2-piece labels for "Formula 12"; and insert leaflets entitled "Weight Control with Ajem's Formula 12."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked part of the article from the drum shipped as above, into the 36 boxes.

LIBELED: 2–11–60, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the repack box label and the printed material described above, contained statements which represented and suggested that the article was an effective appetite depressant and an adequate and effective treatment for obesity; which statements were false and misleading, since the article was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: On or about 2–19–60, Ajem Drug Co., Oakland, Calif., filed a claim to the article and filed an answer denying that the article was misbranded by the above-described repack box label, cards, display cards and leaflets. On or about 11–23–60, the Government filed written interrogatories which were subsequently answered by the claimant. On 12–22–60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey; also, on the same date, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8324. Curb-Wate tablets. (F.D.C. No. 43652. S. No. 57–767 P.)

QUANTITY: 723 90-tablet btls. and 270 45-tablet btls., at Yonkers, N.Y., in posession of Nutrition Products Co.

SHIPPED: Prior to 10–14–59, from Philadelphia, Pa.

LABEL IN PART: "Curb-Wate with Controlene* For effective Appetite Control to aid Weight Reduction. Nutrition Products Co. Yonkers, N.Y. Dist. *Brand of Phenylpropanolamine Hydrochloride (25 mg. per tablet)."

ACCOMPANYING LABELING: Leaflets entitled "Curb-Wate Reducing Plan * * * Automatic Appetitie Regulator"; display cards reading in part "Lose Weight Without Will-Power! New . . . Curb-Wate with Controlene*"; envelopes containing promotional material and business reply envelopes addressed to "Curb-Wate Company, Inc., Special Box 502, Tuckahoe, N.Y."

RESULTS OF INVESTIGATION: The article was manufactured, packed, and shipped on the order of Nutrition Products Co., who supplied the manufacturer with labels, inserts, and display cards.

LIBELED: 11–13–59, S. Dist. N.Y.; libel amended on or about 10–28–60.

CHARGE: 502(a)—when shipped and while held for sale, statements in the labeling of the article, namely, the bottle label, the above-described leaflet in carton, display cards, and envelopes, and the name *"Curb-Wate,"* represented and suggested that the article was an adequate and effective treatment for obesity, and was adequate and effective to cause one to lose weight without feeling hungry, to cause one to lose weight without willpower, to regulate the appetite, to "tranquilize" hunger pangs, to provide automatic appetite control, to automatically reduce calorie intake, to automatically reduce food intake, as an aid in weight reduction, to curb the appetite, to control appetite, to control hunger, to control weight, to control the appetite without any diet whatsoever, without hunger pangs, and deprivation, to keep one away from fattening foods, to do away with the desire to eat excessively, and to save one from being mentally depressed and discouraged while losing weight, which representations and suggestions were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: On 12–23–59, the Curb-Wate Co., Inc., Yonkers, N.Y., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described bottle label, leaflets, display cards, and envelopes. On or about 10–28–60, the Government filed an amended libel and served its written interrogatories upon the claimant. Thereafter, the court granted the claimant's motion for removal of the cause to the United States District Court for the District of New Jersey; also, Nysco Laboratories, Inc., Long Island City, N.Y., was substituted as the party claimant by order of the court. On or about 4–20–61, the claimant filed its answers to the Government's written interrogatories.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28–Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8325. Trimadon capsules. (F.D.C. No. 44209. S. No. 62–113 P.)

QUANTITY: Approximately 44,000 capsules in bulk drums and an undetermined number of plastic boxes, each containing 18 capsules, at Oakland, Calif., in possession of United Pharmaceuticals, Inc.

SHIPPED: 12–7–59, from Long Island City, N.Y.

LABEL IN PART: (Box) "Trimadon Improved An Appetite Suppressant * * * 75 mg. of Phenyl Propanolamine Hydrochloride * * * United Pharmaceuticals, Inc. Oakland, California."

ACCOMPANYING LABELING: Insert leaflets entitled "Weight Control with Trimadon," and display cards entitled "New Trimadon."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked part of the article from bulk stock shipped as above, into plastic boxes. The leaflets and display cards were printed locally.

LIBELED: 2–2–60, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the retail box label, the leaflets, and the display cards described above, contained statements which represented and suggested that the article was an adequate and effective treatment as an appetite depressant; for scientific weight control; and that it would aid in controlling your appetite; which statements were false and misleading since the article was not an adequate and effective treatment for such purposes.

DISPOSITION: On 2–24–60, United Pharmaceuticals, Inc., Oakland, Calif., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described leaflets and display cards. On or about 11–8–60, the Government filed written interrogatories which were subsequently answered by the claimant. On 12–22–60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey; also, on 12–22–60, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8326. Prescription 812 tablets. (F.D.C. No. 44218. S. No. 66–636 P.)

QUANTITY: 25 60-tablet btls. and 8 30-tablet btls., at Pittsburgh, Pa.

SHIPPED: Between 7–23–59 and 11–22–59, from New York, N.Y., by Lloyd-Owen Drug Co., Inc.

LABEL IN PART: "Prescription 812 For Treatment of Overweight and Obesity Each Tablet Contains: Phenylpropanolamine HCl–25 mgm. Sodium Caseinate 1 gr. Dextrose 1 gr. Directions * * * Caution * * * Lloyd-Owen Drug Co., Inc. * * * New York."

ACCOMPANYING LABELING: Leaflets entitled "How To Lose Weight Faster With Prescription 812."

LIBELED: 2–4–60, W. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article, namely, the carton and bottle label, and leaflet in the carton contained statements which represented and suggested that the article was an adequate and effective treatment for overweight and obesity, which statements were false and misleading since the article was not an adequate and effective treatment for these purposes.

DISPOSITION: On or about 3–9–60, Lloyd-Owen Drug Co., Inc., New York, N.Y., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described bottle label and leaflet. On or about 10–14–60, the Government filed written interrogatories which were subse-

quently answered by the claimant. On 11–23–60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey; also, on the same date, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America v. 60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8327. **White Shield Spanorex capsules.** (F.D.C. No. 44217. S. No. 99–183 P.)

QUANTITY: 26 21-capsule plastic boxes, at Paterson, N.J.

SHIPPED: 1–5–60, from New York, N.Y., by White Shield Corp.

LABEL IN PART: "White Shield No. 1250 * * * Spanorex Capsules Appetite Depressant Each capsule contains: Phenylpropanolamine HCl 75 mg. * * * Distributors White Shield Corporation, New York 1, N.Y."

ACCOMPANYING LABELING: Cards reading in part "Spanorex Directions * * * Each capsule contains: * * * Indications for use: Spanorex Capsules aid in weight reduction and control by curbing the appetite * * * See the enclosed suggested sample diet for one day. Caution: * * * White Shield Corporation * * * New York 46262," and leaflets entitled "Suggested Dietary Regimen."

LIBELED: 2–2–60, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling of the article, namely, the box labels, the cards and the leaflets described above, contained statements which represented and suggested that the article was adequate and effective as an appetite depressant, to curb the appetite, and to lose weight, which statements were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: White Shield Corp., New York, N.Y., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described box labels, cards and leaflets. On or about 12–1–60, the Government served written interrogatories upon the claimant. On 12–16–60, the claimant filed its answer to the Government's written interrogatories. On the same date, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8328. **Leen capsules.** (F.D.C. No. 43636. S. No. 48–699 P.)

QUANTITY: 12 drums, each containing 20,000 capsules and an undetermined number of 30-capsule and 60-capsule btls., at Oakland, Calif., in possession of The Ray Drug Co.

SHIPPED: On 9–30–59, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Leen Timed Disintegration An Appetite Suppressant in the dietary control of excess weight * * * Each capsule contains: Phenylpropanolamine HCl 50 mg. * * * The Ray Drug Co., Distributor, Oakland, Calif. 45348."

ACCOMPANYING LABELING: Posters entitled "Reduce and Control Weight"; cards entitled "Only One Capsule a Day"; and leaflets entitled "One Leen a Day" and "Leen Prolonged Action."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked part of the article from the drums shipped as above, into the 30-capsule and the 60-capsule bottles.

LIBELED: 11–9–59, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the designation of the article "*Leen*" and statements in its labeling represented and suggested that the article was adequate and effective in controlling the appetite, and reducing and controlling weight, which designation and statements were false and misleading since the article was not adequate and effective in controlling the appetite, and reducing and controlling weight.

DISPOSITION: On 11–9–59, John R. Murray, t/a The Ray Drug Co., Oakland, Calif., filed a claim to the article, and filed an answer denying that the article was misbranded by the above-described repack bottle label, posters, cards and leaflets. On or about 11–10–60, the Government filed written interrogatories which were subsequently answered by the claimant. On 12–22–60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey; also, on the same date, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as the claimant.

On 2–9–62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .*, (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1–22–63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8329. **Leen capsules.** (F.D.C. No. 44223. S. Nos. 62–114/15 P.)

QUANTITY: 10 display ctns., each containing 12 30-capsule boxes, approximately 10,000 capsules in 30-capsule and 60-capsule boxes, and approximately 100,000 capsules in bulk drums, at Oakland, Calif., in possession of The Ray Drug Co.

SHIPPED: 12–1–59 and 1–13–60, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Repack boxes) "Leen * * * Timed Disintegration Capsules Useful as an aid to help Reduce and Control Weight * * * Each capsule contains: Phenyl Propanolamine 75 Mgm. * * * The Ray Drug Co., Distributors, Oakland, Calif.," and (drums) "Nysco Laboratories, Inc. CF 6458 20M Capsules Lot No. 46942 Nyscaps Timed Disintegration Capsules * * * Indications for Use: Phenyl Propanolamine Nyscaps aid in weight reduction and control by curbing the appetite thereby making it easier to adhere to a low calorie diet."

ACCOMPANYING LABELING: Display cartons, repack boxes, repack labels, and carton inserts entitled "The Leen Plan."

RESULTS OF INVESTIGATION: Investigation indicated that the dealer had repacked part of the article from the above-described bulk drums, into 30-capsule and 60-capsule boxes.

LIBELED: 2-11-60, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained statements which represented and suggested that the article was adequate and effective for appetite control, to curb the appetite, and as an aid in weight reduction, which statements were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: John R. Murray, t/a The Ray Drug Co., Oakland, Calif., filed a claim to the article, and filed an answer denying that the article was misbranded. On or about 11-10-60, the Government filed written interrogatories which were subsequently answered by the claimant. On 12-22-60, a stipulation and order for removal was filed, removing the case to the United States District Court for the District of New Jersey; also, on the same date, an amended notice of claim was filed in which Nysco Laboratories, Inc., Long Island City, N.Y., appeared as claimant.

On 2-9-62, it was agreed by the counsel for the claimant, Nysco Laboratories, Inc., that the determination made by the court after trial in *United States of America* v. *60 28-Capsule Bottles, more or less, etc.—Unitrol . . .* , (*See* D.D.N.J. No. 8316), would govern the disposition of this action without the necessity of any further proceedings in this case, since the same drug, issues, and claimant were involved in both actions. On 1-22-63, the *Unitrol* case having been tried, the court entered an order of condemnation and destruction.

8330. **Diet Master tablets and capsules.** (F.D.C. No. 49780. S. No. 39-304 A.)

QUANTITY: 58 unlabeled plastic cases, each containing 30 brown tablets and 30 clear capsules, and 42 display ctns., at Houston, Tex.

SHIPPED: Between 11-20-63 and 1-29-64, from St. Louis, Mo., by Drugmaster, Inc.

ACCOMPANYING LABELING: Display carton reading in part "Lose Weight! Follow the Vitamin Fortified Diet-Master Reducing Plan Drugmaster"; and inserts and cards in the plastic cases, reading in part, "Diet-Master Reducing Plan Your Guide to Figure Beauty," "Diet-Master Reducing Plan * * * Ingredients * * * Directions * * * Caution," "This Card Is Worth Money To You," and "Your Guide to Figure Beauty."

LIBELED: 3-11-64, S. Dist. Tex.

CHARGE: 502(a)—when shipped, the display carton label, the case inserts and the case cards contained statements, including the name of the article, "*Diet Master*," which were false and misleading in that they represented and suggested that the article was adequate and effective to revitalize energy, neutralize any loss of energy and vitality which may accompany loss of weight, control the appetite, promote figure beauty, that the article was a safe means of proper weight reduction, that a person would lose weight through use of the article and thus promote longevity and reduce the incidence of heart disease, diabetes, and other diseases partially or completely caused by excess weight; whereas the article was not adequate and effective for such purposes and since the statements were otherwise contrary to fact.

DISPOSITION: On 4–29–64, Drugmaster, Inc., claimed the article. On 4–30–64, upon motion of the claimant, the case was transferred to the Eastern District of Illinois.

On 5–20–64, Drugmaster, Inc., filed an answer in which it was denied that the article was misbranded. On 1–19–65, the case having been further transferred on 7–3–64 to the Eastern District of Missouri, a consent decree of condemnation and destruction was filed; on 1–28–65, the article was destroyed.

8331. Acerola Plus tablets and Alertine. (F.D.C. No. 46095. S. Nos. 81–141/2 R, 81–144/5 R.)

QUANTITY: 72 100-tablet btls. and 30 250-tablet btls. of *Acerola Plus;* and 28 8-oz. btls. and 13 16-oz. btls. of *Alertine*, at Cambridge, Mass., in possession of Nature Food Centers.

SHIPPED: Between 6–21–61 and 7–18–61, from Yonkers, N.Y., by American Dietaids Co., Inc.

LABEL IN PART: (Btl.) "Acerola Plus 100 mgs. Natural Vitamin C from Acerola, Rose Hips, Black Currants, Green Peppers and 25 mgs. Hesperidin-Rutin-Citrus Bioflavonoid Complex * * * U.S. Nutrition Products Co., Yonkers, N.Y. Dist."; and "Alertine Net Wt. 8 Oz. (227 gms.) [or "16 oz. (454 gms.)"] U.S. Nutrition Products Company, Yonkers, N.Y. Dist."

ACCOMPANYING LABELING: Leaflet entitled "Net . . . the Fastest Pep Tablets!" and reading in part: "Free! * * * Folk Medicine, by D. C. Jarvis, M.D. * * * Nature Food Centers, * * * Cambridge 42, Mass."; leaflets entitled "Annual Sale 2 for 1 Buy one—Get One Free! * * * Nature Food Centers, * * * Cambridge, Mass." and "Free We Have a Wonderful Gift For You! * * * Sale—Save on 100% All Natural Health Products. * * * Nature Food Centers Cambridge, Mass."

LIBELED: 7–21–61, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the above-described labels and accompanying labeling contained false and misleading representations and suggestions that the article (*Acerola Plus*) was adequate and effective for the treatment and prevention of weak health of the cells of the body, bones, heart, and gallbladder; loss of vitality, pep and energy; lowered resistance to disease; fatigue; bleeding gums and loose teeth; weak blood capillaries; and rundown, worn-out tissues; and that the article (*Alertine*) was adequate and effective as a treatment for loss of memory, forgetfulness and poor concentration when these are symptoms of advanced age; to produce keener mental powers; and help restore youthful alertness.

DISPOSITION: 245 100-tablet bottles and 166 250-tablet bottles of *Acerola Plus* and 110 8-oz. bottles and 5 16-oz. bottles of *Alertine* were seized. The articles were claimed by U.S. Nutrition Products Co., which filed an answer on 9–1–61 denying that the articles were misbranded.

On 9–19–61, upon stipulation of the parties, the case was transferred to the District of New Jersey. On or about 4–23–63, interrogatories were served upon the claimant and, on 9–3–63, the claimant served answers to the Government's interrogatories. On 10–2–64, the claimant having consented to a decree without admitting the charges in the libel, a decree of condemnation and destruction was entered.

8332. Clyr tablets, Arex tablets, Dyna-Zyme tablets, Tecktrol tablets, Dyna-Cal tablets, Super Geriatric tablets, and Maridin tablets. (F.D.C. No. 50555. S. Nos. 104–308/10 A, 104–312/15 A.)

QUANTITY: 15 btls. of *Clyr tablets;* 22 90-tablet btls. and 26 180-tablet btls. of *Arex tablets;* 12 btls. of *Dyna-Zyme tablets;* 44 135-tablet btls. and 46 270-tablet btls. of *Tecktrol tablets*; 5 cases, each containing 12 180-tablet btls., and 3 cases, each containing 12 90-tablet btls., of *Dyna-Cal tablets;* 6 btls. of *Super Geriatric tablets;* and 9 120-tablet btls. and 6 360-tablet btls. of *Maridin tablets*, at Seattle, Wash.

SHIPPED: Between 10–9–62 and 5–26–64, from N. Hollywood, Calif., by Dynamic Nutritional Products.

LABEL IN PART: (Btl.) "90 Tablets Clyr Water-miscible Vitamin A, Vitamin C, Vitamin B_6, Citrus Bioflavonoids * * * For deficiencies of vitamins A, C, and vitamin B_6, one tablet three times daily * * * Formulated and Distributed by Dynamic Products North Hollywood, California"; "Arex Tablets Vitamin A * * * B_1, B_2, C and citrus bioflavonoids * * * Formulated and distributed by Nutritional Products North Hollywood, California * * * In deficiencies of vitamins A, B_1, B_2, and C three tablets daily"; "Dynamic 30 Tablets Dyna-Zyme Enzymatic Digestant Each Dyna-Zyme Tablet contains a coated outer layer consisting of papain, mycozyme, betaine hydrochloride, and methylcellulose for release in the stomach; an enteric coated inner core of pancreatin and extract of ox bile for release in the intestine * * * Formulated & distributed by Dynamic Nutritional Products—North Hollywood, California * * * as an aid in the digestion of starch (carbohydrate), protein and fat, take 1 or 2 Dyna-Zyme Tablets with or just after meals"; "Tecktrol Reducing Plan A Dietary Aid For The Reduction of Excess Weight. A New Formula containing chondrus (Irish Moss), muciloid hemi-cellulose of plantago ovato (psyllium), sterculia (gum karaya) and a hydrophilic colloid, guar * * * Formulated & distributed by Dynamic Products North Hollywood, Calif. Directions"; "Dynamic * * * Tablets Dyna-Cal Organic Phosphorus-free Calcium with Vitamins C, D, and Glutamic Acid Hydrochloride * * * As a dietary supplement Formulated & distributed by Dynamic Nutritional Products North Hollywood, California"; "100 Tablets Dynamic Super Geriatric Vitamin-Mineral Formula A Dietary Food Supplement For Senior Citizens Water- and oil-soluble vitamins, minerals, and other factors * * * Formulated and distributed by Dynamic Products North Hollywood, California"; "Tablets Meridin Containing Natural Iodine * * * Formulated and distributed by Dynamic Nutritional Products North Hollywood, California Directions: One tablet daily as a dietary source of iodine * * * Each tablet provides 0.15 milligram or 1½ times the minimum adult requirement of natural iodine."

ACCOMPANYING LABELING: Leaflets entitled "Teen Age Acne (Vulgaris)," "Your Health Reporter * * * Better Eyesight," and "The Enzymes and Good Digestion"; and pamphlets entitled "Arex The Multiple-Vitamin Formula for Vitamin-Deficient Eyes," "She's discovered 'Dietless Reducing' with Tecktrol," "New Dyna-Cal Phosphorus-Free Calcium Tablets," "Keeping Fit After Forty," and "Fountain of Youth."

RESULTS OF INVESTIGATION: The accompanying literature was shipped at various times with the articles and at various times under separate cover.

LIBELED: 8–26–64, W. Dist. Wash.

CHARGE: *Clyr tablets*, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the leaflet entitled "Teen Age Acne (Vulgaris)," contained

false and misleading representations and suggestions that the article was adequate and effective in treating acne vulgaris; that dietary deficiencies were frequent and widespread among teenagers; and that such deficiencies were an important etiological factor in acne vulgaris.

Arex tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the pamphlet entitled "Arex The Multiple-Vitamin Formula for Vitamin-Deficient Eyes," and the leaflet entitled "Your Health Reporter * * * Better Eyesight," contained false and misleading representations and suggestions that the article was adequate and effective for the treatment and prevention of various eye problems; that any difficulty, symptom, or discomfort of the eyes or vision might be interpreted as a symptom of dietary deficiency which would be effectively treated by the article, and medical attention to such condition might be safely delayed until after the article had been given a prolonged trial; and that the specification of the presence of euphrasia herb as the base of the article suggested that the article was of significant and unusual value for eye diseases.

Dyna-Zyme tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the pamphlet entitled "The Enzymes and Good Digestion," contained false and misleading representations and suggestions that the article was adequate and effective for the prevention, treatment, and mitigation of the discomfort, symptoms, and conditions of essentially all common digestive disturbances, including, but not limited to, inadequate secretion of bile, hydrochloric acid, and enzymes, belching, flatulence, heartburn, cramps and dyspepsia.

Tecktrol tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the pamphlet entitled "She's discovered 'Dietless Reducing' with Tecktrol," contained false and misleading representations and suggestions that the article was adequate and effective for reducing body weight without dietary limitation; and created an anorexigenic effect.

Dyna-Cal tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the pamphlet entitled "New Dyna-Cal Phosphorus-Free Calcium Tablets," contained false and misleading representations and suggestions that the article was adequate and effective in preventing muscle cramps; and that glutamic acid hydrochloride contained in the article was instrumental in the absorption of calcium in the system.

Super Geriatric tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the accompanying pamphlet entitled "Keeping Fit After Forty," contained false and misleading representations and suggestions that the article was adequate and effective in treating or preventing disorders likely to occur in older people, including night blindness; abnormal dryness of of skin; lack of normal resistance to infection; unhealthy mucous membranes; abnormal skeletal structure; excessive bleeding from minor wounds; unhealthy nerves; poor digestion; poor appetite; neuritis; loss of muscle tone; diarrhea; fatigue; irritability; headache; dizziness; dryness of hair; mental depression; insomnia; loss of weight; constipation; weakness; reddening of lips; sores about the mouth; swelling and redness of the tongue; inflammation of the mouth; vague aches and pains; various anemias, including pernicious anemia; sponginess, soreness, and bleeding of the gums; hemorrhages of the nose, mouth, gums, and face; increased susceptibility to infection; fatty degeneration of the liver; gastrointestinal discomfort; dyspepsia; weakened and fragile bones; muscle cramps; thyroid malfunction; diminished mental and physical vigor; hyperirritability; impaired metabolism of carbohydrates; deteriorative

changes in the structure and function of the body which frequently accompany advancing age; that the article would be effective in adding more years to life and more life to years; and that older people had special vitamin-mineral requirements.

Maridin tablets, 502(a)—when shipped, the labeling of the article, namely, the bottle label and the accompanying pamphlet entitled "Fountain of Youth," contained false and misleading representations and suggestions that the article was adequate and effective to increase vitality for purposes of rejuvenation; restoration of youth to the aged; to prevent and treat infirmities of old age; delay the aging process; promote better health, better spirits, more mental and physical energy; prevent and treat sluggish body, slow heart, poor circulation, cold feet and hands, dull and lusterless hair, thin and brittle fingernails, greying and falling hair, weak memory, headaches, constipation; ugly, flabby, soft flesh; depression, falling asleep, and mental laziness, through the use of iodine.

The libel alleged also that another article and the *Maridin tablets* and *Super Geriatric tablets* were misbranded, and that the other article and the *Super Geriatric tablets* were adulterated, under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 11–9–64. Default—destruction.

8333. **Speedac Cold capsules.** (F.D.C. No. 50468. S. Nos. 7–458 A, 9–473 A.)

QUANTITY: Approximately 232,000 capsules in bulk drums and approximately 73,472 capsules in pkgs. of 16 each, at Baltimore, Md., in possession of Carroll Chemical Co.

SHIPPED: 2–17–64, from Brooklyn, N.Y.

LABEL IN PART: (Pkg.) "Speedac * * * Continuous Action Capsules * * * Each capsule contains: Belladonna Alkaloids (Total) 0.16 mgm. Atropine Sulfate 0.024 mgm. Scopolamine Hydrobromide 0.014 mgm. Hyoscyamine Sulfate 0.122 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. * * * Distributed by The Carroll Chemical Company Baltimore, Md."

RESULTS OF INVESTIGATION: The article, after shipment, had been repacked in part from bulk drums into packages labeled as above.

LIBELED: On or about 8–5–64, Dist. Md.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that a single *Speedac Cold capsule* containing the amounts of the ingredients declared in the label would provide approximately 12 hours of continuous relief from nasal congestion; relieved itching, weeping eyes, running or stuffed-up nose; sneezing; and helped drain nasal passages.

DISPOSITION: 10–15–64. Default—destruction.

8334. **Various Alo products.** (F.D.C. No. 50603. S. Nos. 2–077/80 A, 4–802/6 A.)

QUANTITY: 897 6-oz. btls. of *Alo body beautifier*, 1,797 4-oz. btls. of *Alo hands lotion*, 1,997 3-oz. btls, of *Alo legs lotion*, 247 1¼-oz. tubes of *Alo Moisture Plus beauty matte make-up*, 1,497 3-oz. btls. of *Fashion Tan lotion*, 1,097 4-oz. btls. of *Alo Sun Burn lotion*, 997 4-oz. btls. of *After Tan lotion*, 647 2-oz. jars of *New Alo ointment*, and 997 4-oz. tubes of *Alo V shampoo*, at Fort Lauderdale, Fla., in possession of Aloe Creme Laboratories, Inc.

SHIPPED: On various dates between 5–11–64 and 8–3–64, from Milwaukee, Wis.

LABEL IN PART: (Btl., ctn., tube, and jar) "Alo body beautifier [or "Alo hands

the healing lotion"; or "Alo legs"; or "Alo Moisture Plus beauty matte make-up"; or "Fashion Tan A moisturizing and protective lotion"; or "Alo Sun Burn relief The Healing Lotion"; or "After Tan * * * Contents"; or "New Alo Ointment * * * for all types of minor burns * * * Contains 50% or more fresh 'gel' from the Alo Vera leaf"; or "Alo V Lusterizing shampoo"] Distr. [or "Distributed"'] by Aloe Creme Laboratories, Inc. Fort Lauderdale, Florida."

ACCOMPANYING LABELING: String-attached pamphlets entitled "Beauty secret rediscovered * * * The Story of Alo"; reprint entitled "Ancient 'New' Cosmetic Science Catches Up with Indians" run in the New Orleans States, Tuesday, August 19, 1963; reprint, "Spiny Aloe Vera Yields 'Magic' Gel," origin unknown; reprint, "Newest Beauty Aid Comes From a Plant," from the Houston Chronical, date unknown; reprint, "Shampoo From Plant Product is Newest Hair-conditioned Beauty," from the Chicago Daily News, dated Thursday, February 22, 1964, Section Two, Page 17; reprint, "Aloe Creme Gets U.S. Contract," from the Fort Lauderdale News, Sunday, November 4, 1962; reprint, "Cosmetic Industry Praises Development by Aloe Creme," from Sunday November 18, 1962, Fort Lauderdale News; reprint, "Ever Hear of the First-Aid Plant?" from House Beautiful Magazine, July 1963; reprint, "Aged Exotica for the De-Aging of Modern Faces," from Vogue Magazine, March 15; reprint, "Beauty Bazaar," from Harper's Bazaar Magazine, September 1963; reprint, "Beauty Secret Rediscovered Heralds New Era in Skin Care," from The Miami News, Friday, May 15, 1964; reprint, "Aloe Magic May Grow in Your Garden," from Town News, Pompano Beach, Florida, Wednesday, July 12, 1961; reprint, "Just Looking, Thanks," from Evansville Courier, Evansville, Indiana, Friday, May 1, 1964; reprint, "Aloe Vera," from Tropical Living–Homemaker & Gardener, April 1960; pamphlet of sales aids used by salesmen to promote the sale of the product to the consumer entitled, "Alo Symbol of New Life for Skin Beauty Secret Rediscovered . . . Brings New Beauty to Today's Woman"; and booklet entitled, "Ancient Beauty Secret Rediscovered . . . brings New beauty to today's Woman!"

RESULTS OF INVESTIGATION: The accompanying labeling, other than the string-attached pamphlets, were prepared by Alo Creme Laboratories, Inc., for the purpose of promoting sales of the articles.

LIBELED: 10–8–64, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the articles contained false and misleading representations and suggestions as follows: that the article, "Alo body beautifier," instantly softened and smoothed the skin, and was effective in restoring and maintaining the original skin firmness and elasticity; that the article "Alo hands the healing lotion," smoothed rough spots to velvet perfection, even the elbows, protected hands from reddening, roughening burn of harsh detergents and exposure, contained a medication that soothed, healed and beautified the hands, and freed them from unsightly redness and skin abrasions; that the article, "Alo legs," prevented scraped, sore legs if used prior to shaving, and contained the correct amount of healing Aloe Vera gel to quickly heal razor burns, scrapes, nicks and chapped legs; that the article, "Alo Moisture Plus beauty matte make-up," conditioned your skin while you wore it, and removed tiny lines due to premature aging skin; that the article, "Fashion Tan," stimulated the skin and acted to bring the pigment to the surface, affording natural protection while tanning, prevented burning, drying and peeling, allowed the skin to accept up to 50 percent more ultraviolet

rays without damage, acted to prevent premature aging of the skin, and gave you a suntan in much less time without burning, peeling or flaking; that the article, "Alo Sun Burn relief The Healing Lotion," relieved twice as fast as treatment of sunburn, windburn, Portuguese man-of-war, jellyfish stings, insects bites, and minor irritations; that the article, "After Tan," held tan twice as long by stimulating skin and keeping pigment at the surface, and smoothed and overcame fine flaking of the skin due to suntanning; that the article, "New Alo Ointment," changed a deep thermal burn to a minor first or second degree burn within 48 hours by rapid regeneration of tissue, was remarkably effective in treating deep thermal and radiation burns, as well as burns from steam, scalds, acids, chemicals, electricity, and others, and was effective in treating acne, man-of-war stings, jellyfish stings, insect bites, dermatitis, abrasions, minor cuts and chapping, and poison ivy; that the article, "Alo V Lusterizing shampoo," strengthened and revitalized the hair and scalp and brought back youthful texture and body to the hair; and 502 (e) (1) (A) (ii)—the labels failed to bear the established name of each active ingredient.

DISPOSITION: The following quantities of the articles were seized: 7 bottles of *Alo body beautifier;* 5 bottles of *Alo hands lotion;* 3 bottles of *Alo legs lotion;* 14 bottles of *Alo Moisture Plus beauty matte make-up;* 269 bottles of *Fashion Tan lotion;* 50 1-oz., 2 2-oz., 81 3-oz., and 12 4-oz. bottles of *Alo Sun Burn lotion;* 45 bottles of *After Tan lotion;* 98 bottles of *New Alo ointment;* and 31 4-oz. bottles and 70 ½-oz. bottles of *Alo V shampoo.*

On 11–5–64, Aloe Creme Laboratories, Inc., having appeared as claimant, a consent decree which provided for relabeling was entered.

8335. Elastic support devices. (F.D.C. No. 50654. S. No. 42–572 A.)

QUANTITY: 2 ctns. at Provo, Utah.

SHIPPED: 7–3–64, from Holyoke, Mass., by A-T Surgical Co.

LABEL IN PART: (Ctn.) "At Health Products Special Sales Deal No. 7300 With Wire Display Rack Four – A-T Rib Belts—No. 16 Four – A-T Ladies Rib Belts—No. 26 Three – A-T Elbow Caps—No. 20 Four – A-T Anklets—No. 36 Four – A-T Leggings—No. 40 Four – A-T Knee Caps—No. 48 Four – A-T Back Supports—No. 410 —FREE— One – Wire Display Rack—No. 6 Six – A-T Wristlets—No. 12 Twenty – Catalogs No. 164 – for mailing to doctors"; (polyethylene bag) "No. 16 * * * AT Rib Belt Correct Binding Support"; "No. 26 * * * Ladies' AT Rib Belt * * * Manufactured by A.T. Surgical Company, Holyoke, Mass."; "Style No. 20 * * * AT Elbow-Cap"; "Style No. 36 * * * AT Anklet * * * A-T Surgical Co., Holyoke, Mass."; "Style No. 40 * * * AT Legging"; and "Style No. 48 * * * AT Knee-Cap"; (small ctn.) "AT Back Support."

ACCOMPANYING LABELING: Display rack reading "For Quicker Recovery and Better Health AT Health Products Designed to Supply All Correct Effective Support * * * AT Back Support * * * Eliminates Backaches Improves Poor Posture Ideal Support For Obesity Proper Support Where It's Needed Most"; and catalog No. 164 entitled "AT Health Products Highly Endorsed by Doctors * * * For Treatment For Relief For Prevention of Injuries As An Aid To Quicker Healing."

RESULTS OF INVESTIGATION: Examination showed the devices to consist of knit elastic supports intended to be used around various parts of the body to give therapeutic support.

LIBELED: 10–6–64, Dist. Utah.

CHARGE: 502(a)—when shipped, the labeling of the articles, namely, the container and display rack labels and the aforesaid catalogs identified as "No. 164," accompanying the articles, contained false and misleading representations that the article, "*Rib Belts*" (No. 16 and No. 26), gave instant relief in the treatment of rib injuries, after chest surgery, chest contusions, pleurisy, intercoastal neuralgia, fractured sternum, and fractures and embolism in cases of bedridden convalescence; that the article, "*Elbow Cap*," was adequate and effective as a treatment for stiff, strained or weak elbows, pains of arthritis, rheumatism, neuralgia, and that its use would quicken the healing process; that the article, "*Anklet*," was adequate and effective to promote faster healing; that the article, "*Legging*," had complete therapeutic value to prevent distention and alleviate painful symptoms after surgery or injection treatments, and that its use gave healthy support for varicose veins, aching, throbbing and swollen legs, varicose ulcers, and phlebitis, and prevented embolism in cases of bedridden convalescence; that the article, "*Knee Cap*," was adequate and effective to promote faster healing and gave instant relief for sprains and swellings, after knee surgery, and after cartilage removal; and that the article, "*Back Supports*," was adequate and effective to eliminate backache, sagging back muscles, and gave immediate relief in obesity, fallen stomach, postoperative abdominal incisions, ventral hernia, sacroiliac and lumbosacral conditions, post-disc operation, and ptosis of kidney.

DISPOSITION: 12–7–64. Default—destruction.

8336. Bath aerator device. (F.D.C. No. 50841. S. No. 37–301 A.)

QUANTITY: 1 device at Houston, Tex., in possession of Vitamin Specialties Co.

SHIPPED: 5–11–62, from Seattle, Wash.

ACCOMPANYING LABELING: Window display sign reading in part "Arthritis–Sore Muscles–Rheumatism–Nervous Tension–Poor Circulation Hydro-Massage For Home Use Bubble Your Troubles Away"; brochure entitled "You Are As Young As You Feel"; leaflet entitled "Presentation For Aqua-Laxer"; newspaper reprint entitled "Aqua-Laxer Hydro-Massage"; leaflet entitled "Aqua-Laxer Hydro-Massage," and various testimonial letters.

RESULTS OF INVESTIGATION: The article consisted of a perforated plastic mat, a flexible hose, and a motor-driven air blower. The device produced a flow of air bubbles in bath water.

The window display sign had been used by Mrs. C. P. Malone, proprietor of Vitamin Specialities Co. and owner of the device, to promote the sale of the device.

LIBELED: 11–25–64, S. Dist. Tex.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for poor circulation, muscle fatigue, arthritis, rheumatism, bursitis, neuritis, mental and physical tension, backaches, varicose veins, nervous conditions, and sinus congestion; and that use of the article would improve health and vitality; make you feel younger; tranquilize; cleanse the muscle tissues; prevent discomforts; and was like a fountain of youth.

DISPOSITION: 12–31–64. Upon motion of the Government and consent of the owner of the device, the court ordered the dismissal of the action, the return of the device to the owner, the destruction of the sign, and the imposition of costs of publication upon the owner.

8337. Gilbert Hydro Massage Bath Unit device. (F.D.C. No. 50007. S. No. 24–213 A.)

QUANTITY: 2 devices at Chicago, Ill.

SHIPPED: 3–19–64, from St. Louis, Mo., by Gilbert Steambath Co., Inc.

LABEL IN PART: (Ctn. and device) "Gilbert Hydro Massage Bath Unit * * * A product of Gilbert Steambath Co. * * * St. Louis, Missouri"; (timing device) "The Gilbert Hydrobath Massage St. Louis, Mo."

ACCOMPANYING LABELING: Directions for installation and booklets entitled "The Gilbert Steambath Company."

RESULTS OF INVESTIGATION: The device consisted of a timer controlling an electric pump which forced water through an aerator and tubing intended to be placed in the bottom of a bathtub. In use, aerated water was forced against the body with mild pressure.

LIBELED: 5–1–64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for water-healing for curative purposes, and for the treatment of diseases such as poor circulation, arthritis with stiff, swollen joints, sprains, joint and bone injuries, neuritis, weak and painful feet, stiffness, muscle spasms, adhesions, infected wounds, and many other ailments.

DISPOSITION: 10–20–64. Consent—claimed by Gilbert Steam Bath Co. and ordered released under bond for relabeling.

8338. Hydro-Life massage device. (F.D.C. No. 50409. S. No. 61–317 A.)

QUANTITY: 8 devices, 8 plastic trays, and 10 plastic hoses, at Beverly Hills, Calif., in possession of Hydrolife Products Co.

SHIPPED: Prior to 7–24–64, from Cleveland, Ohio, by Royal Appliance Co.

LABEL IN PART: (Tray and device) "Hydro-Life."

ACCOMPANYING LABELING: Booklets entitled "Hydrolife, a stimulating experience in hydro-massage"; leaflets entitled "Enjoy a new experience in Relaxation with Hydrolife" and "A new sensation in Hydromassage"; looseleaf-type sales manual and extra copies of several of the pages, namely, "Hydrolife Fact Sheet," "The Use of the Whirlpool Bath," "Relax . . . for Health!" "The Whirlpool Bath," "Questions and Answers," "Testimonials," "A New Sensation in Hydro Massage," "These Treatments," "Remarkable Relief from Minor Arthritis Pains," "Unwind Those Nerves," "The Better Way," "Dramatic New Whirlpool Hydromassage"; and posters entitled "Hydrolife Therapeutic Bath" and "The Successor to Whirlpool Bathing."

RESULTS OF INVESTIGATION: The article consisted of a vacuum cleaner motor housed in a fiber glass case, a plastic-covered wire hose, and a hollow plastic slab (or tray) containing holes to expel air into the water. The slab was attached to the hose and placed on the bottom of the bathtub. The hose was then to be attached to the power unit, and the motor switch on the timer was turned on.

The leaflets, booklets, and sales manual were shipped by Royal Appliance Co., and the posters and extra pages of the sales manuals were prepared on the order of the dealer.

LIBELED: 7–29–64, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for traumatic sprains, strains and contusions; synovitis; bursitis; bone injuries and postfractures; circulatory disturbances, such as inflammation, edema, ulcers, arteriosclerosis, and other peripheral vascular diseases; relief of painful joints; scar tissue; adhesions; peripheral nerve injuries; neuritis; arthritis; postpoliomyelitis spasm, and other similar conditions; gout; myositis; neuromyositis; stiff, swollen, enlarged and tender joints; polio; broken limbs; emphysema; diabetes; and that use of the device would enable the user to get more mileage out of his years and more years out of his life; and that it provided the vibration, pulsation and manipulation of the practiced fingers of an expert masseur; that it provided neural stimulation and softened ligaments; and that nervous tensions, hectic pressures and occupational fatigue seemed to vanish with the use of the device.

DISPOSITION: 11–20–64. Default—destruction.

8339. McKune Whirlpool Bath device. (F.D.C. No. 50129. S. No. 51–756 A.)

QUANTITY: 5 devices, at Wyoming, Mich.

SHIPPED: 3–5–64 and 3–13–64, from Chicago, Ill., by John J. McKune & Sons Co., Inc.

LABEL IN PART: (Device) "McKune Whirlpool Bath Unit John J. McKune & Sons Co., Inc., Chicago, Illinois."

ACCOMPANYING LABELING: Brochures entitled "Whirlpool Hydro-Massage"; leaflets entitled "McKune Whirlpool Bath Units"; display placards reading in part "McKune Whirlpool Hydro-Massage * * * If you suffer pains from Poor Circulation, Tired Feet, Chronic Arthritis, Aching Back," "Arthritis," "Poor Circulation," "Rheumatism," "Tired Feet," "Tension Headaches," "Muscular Fatigue," "Aching Back," and "Can't Sleep."

RESULTS OF INVESTIGATION: The device consisted of an electric motor enclosed in a small carrying case to which was attached a flexible hose which terminated in a section of tubing. In use, the tubing was placed in the bottom of the bathtub, and the pumping action resulted in agitation of the water.

The placards reading "McKune Whirlpool, etc.," were shipped by John J. McKune & Sons Co., Inc., and the placards reading "Arthritis," "Poor Circulation," etc., were prepared locally.

LIBELED: 5–13–64, W. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment in overcoming poor circulation; relieving tired feet, chronic arthritis, aching back, rheumatism, tension headaches, muscular fatigue, and insomnia.

DISPOSITION: 10–21–64. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE*

8340. Animal Vimin With Kelp. (F.D.C. No. 50661. S. No. 42–534 A.)

QUANTITY: 800 bags at Provo, Utah.

SHIPPED: 8–7–63, from Battle Mountain, Nev.

LABEL IN PART: "Animal Vimin With Kelp Poultry and Livestock Food Supplement Formulated to promote health development of pets, poultry and livestock * * * Usage: 1 to 5% added to basic feed * * * Vitamins A 2,600 USP Units per pound * * * Riboflavin 136 mg. per pound * * * 50 Lbs. Net."

ACCOMPANYING LABELING: Leaflets entitled "Animal Vimin With Kelp Poultry & Livestock Food Supplement."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 30 percent vitamin A and less than one percent riboflavin of the declared amounts of these ingredients.

The above-described leaflets were received for the purpose of promoting sales of the article, from Eugene Peterson, national distributor for Animal Vimin, under the name National Additive Corp. Des Moines, Iowa.

LIBELED: 10–7–64, Dist, Utah.

CHARGE: 502(a)—while held for sale, the accompanying labeling, namely, the leaflet described above, contained false and misleading representations that the article was adequate and effective to decrease animal susceptibility to disease and that the article was an adequate and effective substitute for the use of antibiotics in poultry.

The libel alleged also that the article was misbranded under provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12–7–64. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 8281 TO 8340

PRODUCTS

*See also Nos. 8313–8315.

[1] (8283, 8290, 8292, 8301, 8317–8331) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8283, 8290, 8292, 8301, 8317–8331) Seizure contested.
[2] (8316) Seizure contested. Contains opinion of the court.

[1] (8283, 8290, 8292, 8301, 8317–8331) Seizure contested.

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[1] (8283, 8290, 8292, 8301, 8317–8331) Seizure contested.

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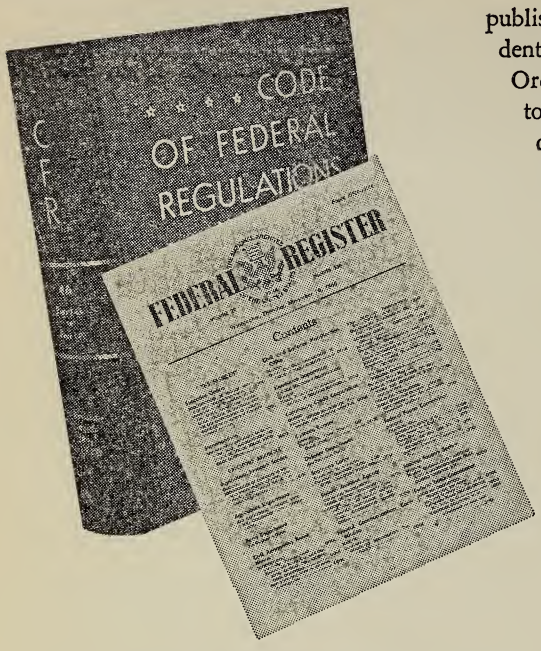

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8341–8380

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 27, 1966.*

CONTENTS

213–834—66

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8341. (F.D.C. No. 49865. S. Nos. 46–027/8 V.)

INFORMATION FILED: 5–14–64, W. Dist. Mo., against **Russell W. Pickard, Joplin, Mo.**

CHARGE: Between 5–28–63 and 5–31–63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–22–65. Probation for 18 months.

8342. (F.D.C. No. 49866. S. Nos. 46–902 X, 47–568 X.)

INFORMATION FILED: 5–14–64, W. Dist. Mo., against **Ray L. Pence, Joplin, Mo.**

CHARGE: Between 6–4–63 and 9–11–63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–22–65. Probation for 18 months.

8343. (F.D.C. No. 51239. S. Nos. 14–521/3 B.)

INFORMATION FILED: 6–1–65, Dist. Colo., against **Bob Bogert, Denver, Colo.**

CHARGE: Between 2–23–65 and 2–26–65, *amphetamine sulfate tablets* were dispensed 3 times without prescriptions.

PLEA: Not guilty.

DISPOSITION: The case came to trial before the court and jury on 9–14–65, and on 9–15–65, the jury returned a verdict of guilty. On 10–4–65, the court denied defendant's motion for a new trial and on 11–19–65, the defendant was sentenced to 90 days in prison.

8344. (F.D.C. No. 48151. S. Nos. 79–356/7 R, 4–423/4 T.)

INDICTMENT RETURNED: 10–30–63, N. Dist. W. Va., against **Arley Nemo and Catherine Carman (truck stop employees), Triadelphia, W. Va.**

CHARGE: Between 5–3–61 and 3–28–62, *amphetamine sulfate tablets* and *dextro-amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty by each defendant to dispensing each drug one time.

DISPOSITION: 11–18–63. Each defendant placed on probation for 2 years.

8345. (F.D.C. No. 51040. S. Nos. 56–609/13 A, 59–862 A, 59–864 A.)

INFORMATION FILED: 4–14–65, S. Dist. Iowa, against **John G. Virden and Phillip W. Watters, Des Moines, Iowa.**

CHARGE: Between 4–21–64 and 5–25–64, *amphetamine sulfate tablets* were dispensed 3 times without prescriptions.

PLEA: Guilty by Watters to 1 count; by Virden to 2 counts.

DISPOSITION: 9–22–65. Each defendant—sentence of 1 year's imprisonment, of which 10 months was suspended, probation for 2 years, and court costs.

8346. (F.D.C. No. 51041. S. Nos. 35–306/9 A.)

INFORMATION FILED: 8–9–65, W. Dist. Ky., against **Ralph Poteet and John W. Wayne (employees of a service station), Middletown, Ky.**

CHARGE: On 2-28-64 and 3-6-64, *amphetamine sulfate tablets* and *dextroamphetamine sulfate capsules* were each dispensed twice without prescriptions.

PLEA: Guilty.

DISPOSITION: 10-14-65. Poteet—$400 fine; Wayne—$150 fine.

8347. (F.D.C. No. 50812. S. Nos. 62-174/5 A, 62-177/8 A, 62-180 A, 63-889 A.)

INFORMATION FILED: 12-14-64, Dist. Ariz., against **James G. McGough, Phoenix, Ariz.**

CHARGE: Between 11-20-64 and 11-30-64, *amphetamine sulfate tablets* were dispensed 3 times, *Dexedrine Spansule capsules* were dispensed twice, and *Dexamyl Spansule capsules* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 2-18-65 and, at the conclusion of the trial on 2-19-65, the jury returned a verdict of guilty. On 3-8-65, the court denied defendant's motion for a new trial and imposed a sentence of 3 years in jail. The court also provided for probation of the defendant upon the completion of the jail sentence.

8348. (F.D.C. No. 50607. S. Nos. 42-241 A, 42-243/4 A.)

INFORMATION FILED: 12-9-64, Dist. Colo., against **Robert Eugene Murphy, Denver, Colo., and Terre Haute, Ind.**

CHARGE: Between 3-4-64 and 3-9-64, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: The case was transferred from Dist. Colo. to S. Dist. Ind. On 1-26-65, the defendant was sentenced to 1 year in prison, suspended, and probation for 1 year.

8349. (F.D.C. No. 50614. S. Nos. 61-202/3 X, 61-205/6 X, 61-209 X, 54-802 A.)

INFORMATION FILED: 12-22-64, W. Dist. Mo., against **Mrs. Clara Tanner Pye, and George A. De Feo, Jr., Kansas City, Mo.**

CHARGE: Between 10-2-63 and 1-6-64, *amphetamine sulfate tablets* were dispensed 5 times and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty by Mrs. Pye to 2 counts; by De Feo to 5 counts.

DISPOSITION: 1-29-65. De Feo—1 year in prison, 10 months of which was suspended, and probation for 2 years; Mrs. Pye—probation for 1 year.

8350. (F.D.C. No. 50493. S. Nos. 28-260 X, 29-122/6 X, 56-449 A.)

INFORMATION FILED: 11-12-64, Dist. Kans., against **Kenneth E. Wiemerslage, D.C., Newton, Kans.**

CHARGE: Between 10-23-63 and 5-5-64, *amphetamine sulfate tablets* were dispensed 5 times and *secobarbital sodium capsules* and *ergot tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-5-65. 1 year in prison, 10 months of which was suspended, and probation for 3 years.

8351. (F.D.C. No. 50183. S. Nos. 68-961 T, 68-963 T, 68-965 T, 68-967 T, 13-203 V, 14-941/2 X.)

INFORMATION FILED: 8-12-64, N. Dist. Ill., against **James Pitts, Calumet City, Ill.**

CHARGE: Between 5-24-62 and 9-24-63, *amphetamine sulfate tablets* were dispensed 7 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2-24-65. 6 months in prison and probation for 4 years.

8352. (F.D.C. No. 50366. S. No. 70-442 V.)

INFORMATION FILED: 9-8-64, S. Dist. Ohio, against **James D. Causey, Greensboro, N.C.**

CHARGE: On 2-20-63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-1-65. $500 fine, sentence of 1 year in jail, suspended, and probation for 1 year.

8353. (F.D.C. No. 50633. S. Nos. 4-678/80 X.)

INFORMATION FILED: 11-3-64, W. Dist. N.C., against **Glenn Virgil Walker, Wilmington, N.C.**

CHARGE: On 12-11-63, *amphetamine sulfate tablets* were dispensed once without a prescription at Charlotte, N.C.

PLEA: Guilty.

DISPOSITION: The defendant waived trial in the W. Dist. N.C., and requested and was granted a transfer of the case to the E. Dist. N.C. On 6-11-65, he was fined $350, and placed on probation for 3 years.

8354. (F.D.C. No. 50635. S. Nos. 16-921 V, 16-923 V, 16-941/2 X.)

INFORMATION FILED: 2-4-65, S. Dist. Ohio, against **Ray L. Yoho, Springfield, Ohio.**

CHARGE: Between 5-22-63 and 6-15-63, *amphetamine sulfate tablets* and *dextro-amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-14-65. Probation for 2 years.

8355. (F.D.C. No. 51346. S. Nos. 5-715 A, 5-738 A, 5-750 A, 5-752 A.)

INFORMATION FILED: 7-26-65, S. Dist. Ga., against **Fairley Cisco, Folkston, Ga.**

CHARGE: Between 9-23-64 and 11-4-64, *amphetamine sulfate tablets* were dispensed 3 times and *dextro-amphetamine sulfate capsules* were dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 9-21-65. $750 fine, and probation for 2 years.

8356. (F.D.C. No. 51362. S. Nos. 6-571/7 B, 6-579 B.)

INFORMATION FILED: 8-18-65, Dist. Kans., against **Joe L. Boutros, Wichita, Kans.**

CHARGE: Between 2-5-65 and 3-5-65, *amphetamine sulfate tablets* were dispensed 7 times and *amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10-1-65. $800 fine, and probation for 3 years.

8357. (F.D.C. No. 51558. S. No. 24-572 B.)

INFORMATION FILED: 7-15-65, W. Dist. Ark., against **Carrol C. Worthy (veterinary supply dealer), Springdale, Ark.**

CHARGE: On 6-8-65, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-27-65. $500 fine.

8358. (F.D.C. No. 51364. S. Nos. 34-641/3 B.)

INFORMATION FILED: 8-3-65, N. Dist. Ohio, against **Leo M. Levi, Celina, Ohio.**

CHARGE: Between 1-29-65 and 2-3-65, *dextro-amphetamine sulfate tablets* were dispensed 3 times without prescriptions.

PLEA: Guilty.

DISPOSITION: 9-3-65. $500 fine, and probation for 2 years.

8359. (F.D.C. No. 51056. S. Nos. 94-181/2 A.)

INFORMATION FILED: 9-19-65, E. Dist. Mo., against **Guy D. Greenwood, Hannibal, Mo.**

CHARGE: Between 9-17-64 and 10-1-64, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10-18-65. Imprisonment for 1 year and 4 months.

8360. (F.D.C. No. 51228. S. Nos. 26-421/5 A.)

INFORMATION FILED: 8-13-65, N. Dist. Ill., against **Samuel S. Swislow, t/a Plaisance Pharmacy, Chicago, Ill.**

CHARGE: Between 5-15-64 and 6-22-64, *dextro-amphetamine sulfate tablets* were dispensed 4 times and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-2-65. $200 fine, plus costs, and probation for 2 years.

8361. (F.D.C. No. 51023. S. Nos. 72-985/8 A, 72-990 A.)

INFORMATION FILED: 3-5-65, N. Dist. Miss., against **James G. Shankle, t/a Bena Drug Store, Itta Bena, Miss.**

CHARGE: Between 5-19-64 and 7-1-64, *dextro-amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–12–65. $1,200 fine, and 9 months in prison.

8362. (F.D.C. No. 50625. S. Nos. 37–443/9 A, 40–545 A.)

INFORMATION FILED: 12–14–64, W. Dist. Okla., against **Harry Dean Alexander, Oklahoma City, Okla.**

CHARGE: Between 3–24–64 and 4–21–64, *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription; *secobarbital sodium capsules* were dispensed 3 times; and *meprobamate tablets* were dispensed twice upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3–15–65. $200 fine.

8363. (F.D.C. No. 51026. S. Nos. 30–952 X, 30–957 X.)

INFORMATION FILED: 7–26–65, S. Dist. Calif., against **Vernon I. Cross, t/a Cross Pharmacy, San Pedro, Calif.**

CHARGE: Between 11–12–63 and 11–30–63, *Dexedrine Spansule capsules* and *penicillin tablets* were each dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 8–30–65. $200 fine suspended.

8364. (F.D.C. No. 50643. S. Nos. 6–262 X, 6–264/6 X, 7–672 X, 7–674/76 X, 8–069 X.)

INFORMATION FILED: 4–2–65, Dist. Mass., against **Diamond Pharmacy, Inc., a corporation, Randolph, Mass., Melvin Diamond (president), and Hartley Ligols (pharmacist).**

CHARGE: Between 9–4–63 and 12–20–63, *Librium Hydrochloride capsules* and *Miltown tablets* were each dispensed 4 times, and *Biphetamine 12½ capsules* were dispensed once upon request for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 6–15–65. Corporation—$1,000 fine; Diamond—$500 fine; Ligols—$250 fine.

8365. (F.D.C. No. 51323. S. Nos. 30–688/98 A.)

INFORMATION FILED: 8–10–65, W. Dist. Ky., against **Trover Clinic, Inc., t/a Earlington Pharmacy, Emerson A. Reynolds and John A. Westerfield (pharmacists), Earlington, Ky.**

CHARGE: Between 7–13–64 and 9–22–64, *Librium Hydrochloride capsules* were dispensed 7 times, *thyroid tablets* were dispensed 3 times, and *prednisone tablets* were dispensed once without prescriptions.

PLEA: Guilty by Reynolds and Westerfield to 3 counts each; nolo contendere by Trover Clinic, Inc., to 11 counts.

DISPOSITION: 9–13–65. Corporation—$1,100 fine; individuals—$300 fine each.

8366. (F.D.C. No. 51349. S. Nos. 33–847/8 A, 109–541 A, 109–543/8 A.)

INFORMATION FILED: 8–18–65, S. Dist. Ohio, against **David M. Shuck, t/a Mark's West End Pharmacy, Cincinnati, Ohio.**

CHARGE: Between 7–31–64 and 10–1–64, *Librium Hydrochloride capsules* were dispensed 5 times and *thyroid tablets* were dispensed 4 times without prescriptions.

PLEA: Guilty.

DISPOSITION: 9–9–65. Probation for 6 months.

8367. (F.D.C. No. 51330. S. Nos. 108–661/3 A.)

INFORMATION FILED: 8–10–65, W. Dist. Ky., against **Alvin J. Kruse, t/a Hawesville Drug Store, Hawesville, Ky.**

CHARGE: Between 7–22–64 and 8–10–64, *Librium Hydrochloride capsules* were dispensed twice and *Miltown tablets* were dispensed once without prescriptions.

PLEA: Nolo contendere.

DISPOSITION: 9–13–65. $300 fine.

8368. (F.D.C. No. 51027. S. Nos. 14–283 A, 14–286 A, 14–292/4 A, 15–604/5 A, 15–608 A.)

INFORMATION FILED: 4–2–65, Dist. Mass., against **Benjamin Brenner, t/a Nelson Pharmacy, Charlestown, Mass.**

CHARGE: Between 5–19–64 and 8–19–64, *Librium Hydrochloride capsules* and *Dexedrine Sulfate tablets* were each dispensed twice upon requests for prescription refills without authorization by the prescriber, and *AM Plus Improved capsules* were dispensed 3 times and *Dexedrine Spansule capsules* were dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 7–12–65. Six months jail sentence suspended, probation for 2 years, and $500 fine.

8369. (F.D.C. No. 48887. S. Nos. 55–276/78 R, 61–284 R, 61–291/95 R.)

INFORMATION FILED: 7–16–63, Dist. Alaska, against **Professional Pharmacy, Inc., Juneau, Alaska, and John S. Simpson (president).**

CHARGE: Between 7–8–61 and 7–20–61, *meprobamate tablets* were dispensed 5 times, *dextro-amphetamine sulfate tablets* were dispensed 3 times, and *secobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty by corporation to 6 counts; by individual to 3 counts.

DISPOSITION: 5–5–65. Corporation—$1,000 fine; individual—$500 fine.

8370. (Inj. No. 480.)

COMPLAINT FOR INJUNCTION FILED: 5–5–65, Dist. Alaska, against **Professional Pharmacy, Inc., Juneau, Alaska, and John S. Simpson (president), William M. Whitehead, M.D., Robert R. Smalley, M.D., and Henry Wilde, M.D.**

NATURE OF BUSINESS: The complaint alleged that Professional Pharmacy, Inc., was an Alaska corporation which operated a drugstore at Juneau, Alaska; that John S. Simpson was the president of Professional Pharmacy, Inc.; that he managed and controlled the drugstore, and that he was not licensed as a pharmacist.

The complaint alleged that William M. Whitehead, M.D., Robert R. Smalley, M.D., and Henry Wilde, M.D., were physicians licensed to practice medicine in the State of Alaska; that they were associated with the Juneau Clinic which was located in Juneau, Alaska, in close proximity to the drugstore operated by Professional Pharmacy, Inc.; that Professional Pharmacy, Inc., stocked and dispensed prescription drugs such as *dextro-amphetamine sulfate*

tablets, meprobamate tablets, and *secobarbital sodium capsules,* all of which were manufactured outside the State of Alaska and were brought into the State for sale; and that Federal law required that such drugs be dispensed only on prescription.

CHARGE: The complaint alleged that the defendants engaged in the following practices which resulted in violations of the Federal Food, Drug, and Cosmetic Act:

(1) A customer would come into the drugstore operated by Defendant Professional Pharmacy, Inc., and would ask Defendant Simpson for a prescription drug such as Dexedrine, Equanil, or Seconal.

(2) If the customer did not have a prescription, Simpson would state that Federal law required a prescription for such a drug and that he would have to fix up a prescription for the customer.

(3) Simpson would sometimes obtain the customer's name and telephone one of the physicians who are defendants herein. Simpson would tell the physician he had a friend in the store, state the name of the customer, and ask for authorization to dispense a certain quantity of the drug. The physician would then authorize the dispensing of the drug and Simpson would write out a "prescription" for the customer and would sign the physician's name on the "prescription." Simpson would dispense the drug in a vial labeled "Use as directed."

(4) Simpson would sometimes obtain the customer's name, write out a "prescription," sign a physician's name, and dispense the drug without informing the physician. Simpson would later obtain a physician's signature on the "prescription," which might or might not be the signature of the physician whose name he had originally written on the "prescription."

(5) When a customer asked for Seconal (secobarbital sodium capsules), Simpson would say, "I am afraid the doctor would not go for these," but he would then dispense the drug. Later he would prepare a "prescription" and obtain a physician's signature thereon.

(6) Simpson would also dispense refills and double refills on the basis of such "prescriptions" without contacting a physician.

(7) There were some other variations in these practices. Sometimes Simpson dispensed the drug in an unlabeled vial. Sometimes he dispensed the drug in the manufacturer's original bottle bearing the manufacturer's original label. Sometimes the customer told Simpson the drug was for the use of the customer's wife.

(8) In the course of these practices, the doctor never saw the "patient"; the doctor was not informed as to the "patient's" physical condition, medical history, mental condition, or genuine drug needs; the doctor gave no directions for use; and the doctor did not know whether the drug was contraindicated for the person who was to use it. A bona fide doctor-patient relationship did not exist.

DISPOSITION: On 5–5–65, a consent decree of permanent injunction was filed, the defendants having appeared in this proceeding and consented to the entry, although they did not admit the allegations in the complaint and they asserted that they at no time knowingly or intentionally violated the Federal Food, Drug, and Cosmetic Act. The decree perpetually enjoined and restrained the defendants, their agents, employees and representatives from causing *secobarbital sodium capsules, dextro-amphetamine sulfate tablets, meprobamate tablets,* or any other drug which was a prescription drug within the

meaning of section 503(b)(1), to become misbranded while held for sale after shipment in interstate commerce by participating in any practice which resulted in such drug being dispensed pursuant to a "prescription" which was not a valid prescription because it was not based upon a bona fide doctor-patient relationship.

8371. (F.D.C. No. 49875. S. Nos. 8-247 V, 8-249/50 V, 56-106/7 V, 6-741 X, 6-744/6 X.)

INFORMATION FILED: 10-27-64, Dist. Mass., against **John F. Burke, t/a Burke's Pharmacy, Boston, Mass., and William C. Connors (pharmacist).**

CHARGE: Between 3-26-63 and 6-26-63, *Miltown tablets* were dispensed 5 times, and *Seconal Sodium capsules* were dispensed twice, upon requests for prescription refills without authorization by the prescriber; and *penicillin tablets* and *Premarin tablets* were dispensed once each without a prescription.

PLEA: Guilty by Burke to all counts; by Connors to 1 count involving *Miltown tablets* and to the counts involving *Seconal Sodium capsules, penicillin tablets,* and *Premarin tablets.*

DISPOSITION: 1-4-65. Burke—imprisonment for 6 months, suspended, and probation for 2 years; Connors—imprisonment for 3 months, suspended, and probation for 2 years.

8372. (F.D.C. No. 50465. S. Nos. 56-009/11 V, 56-350 V, 56-352/4 V, 7-131 X.)

INFORMATION FILED: 9-23-64, Dist. R.I., against **Atom Drug Co. (a partnership), Warwick, R.I., Norman Miller and Saul Miller (partners).**

CHARGE: Between 4-18-63 and 6-3-63, *Miltown tablets* were dispensed 4 times, *amphetamine sulfate capsules* were dispensed 3 times, and *Meticorten tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-21-65. Partnership—$400 fine; individuals—$400 fine each.

8373. (F.D.C. No. 49544. S. Nos. 44-672 T, 44-757 T, 81-643 T.)

INFORMATION FILED: 9-4-64, E. Dist. Pa., against **Leonard Hoffman, t/a Hoffman Apothecary, Upper Darby, Pa.**

CHARGE: Between 6-15-62 and 8-2-62, *Miltown tablets, Tuinal capsules,* and *Metandren tablets* were each dispensed once upon request for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: 6-16-65. $500 fine, and probation for 1 year.

8374. (F.D.C. No. 50782. S. Nos. 6-566 X, 6-568 X, 6-571 X, 8-105/7 X, 8-111/12 X, 12-441 A, 13-677 A.)

INFORMATION FILED: 4-2-65, Dist. Mass., against **Kerrigan's Pharmacy, Inc., t/a Kerrigan's Corner Pharmacy, Daniel Wine (president-treasurer), and Lynn Goren (pharmacist), Milton, Mass.**

CHARGE: Between 9-30-63 and 1-20-64, *Miltown tablet*s were dispensed 6 times and *Nembutal Sodium capsules* were dispensed 4 times upon requests for prescription refills without obtaining authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 10-13-65. Corporation—$1,000 fine; Wine—$500 fine, and 2 years' probation; Goren—$100 fine.

8375. (F.D.C. No. 50490. S. Nos. 6–130 A, 6–134 A, 6–138 A.)

INFORMATION FILED: 11–19–64, S. Dist. W. Va., against **Thomas G. Matney, M.D., Peterstown, W. Va.**

CHARGE: Between 2–27–64 and 3–5–64, *pentobarbital sodium capsules* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–14–65. Probation for 18 months.

8376. (F.D.C. No. 50784. S. Nos. 37–453/8 A.)

INFORMATION FILED: 12–29–64, W. Dist. Okla., against **Albert K. Davis (pharmacist), Oklahoma City, Okla.**

CHARGE: Between 4–9–64 and 4–28–64, *pentobarbital sodium capsules* and *meprobamate tablets* were dispensed 3 times each, upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3–1–65. $150 fine.

8377. (F.D.C. No. 51367. S. Nos. 36–485 A, 36–487/89 A, 36–491/92 A.)

INFORMATION FILED: 8–9–65, W. Dist. Okla., against **John M. Robinson and James B. Robinson (partners in the partnership of Robinson Bros. Drug), Oklahoma City, Okla.**

CHARGE: Between 9–28–64 and 10–13–64, *Biphetamine 20 capsules* and *secobarbital sodium capsules* were each dispensed 3 times upon requests for refills of prescriptions without authorization by the prescriber.

PLEA: Nolo contendere by each defendant to 3 counts.

DISPOSITION: 8–30–65. Each defendant—$300 fine.

8378. (F.D.C. No. 51322. S. Nos. 156–821/2 A, 23–461 B, 23–463/4 B.)

INDICTMENT RETURNED: 9–9–65, S. Dist. Tex., against **Worth Woolsey (operator of a truck stop) and John J. Jalufka (employee), Rosenberg, Tex.**

CHARGE: On 12–12–64 and 1–5–65, *Biphetamine 20 capsules* were dispensed 3 times and *dextro-desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty by Woolsey to 2 counts; by Jalufka to 3 counts.

DISPOSITION: 10–22–65. Jalufka—1 year in prison suspended, 30 days in prison to be served, and probation for 5 years; Woolsey—1 year in prison suspended, 30 days in prison, to be served, $400 fine, and probation for 5 years.

8379. (F.D.C. No. 48883. S. No. 597 T.)

INFORMATION FILED: 9–24–63, N. Dist. Ga., against **Charles Wesley Turner (service station employee), Haralson, Ga.**

CHARGE: On 6–1–62, *Diphetamine tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–18–64. Probation for 1 year.

8380. (F.D.C. No. 50644. S. Nos. 37–423/31 A.)

INFORMATION FILED: 2–26–65, W. Dist. Okla., against **Jim J. Orf, t/a Indiana Pharmacy, Oklahoma City, Okla., and Mrs. Dora C. Aikman (pharmacist).**

CHARGE: Between 4–9–64 and 4–28–64, *secobarbital sodium capsules* were dispensed 5 times, and *pentobarbital sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Orf to 9 counts; by Mrs. Aikman to 5 counts.

DISPOSITION: 4–6–65. Orf—$225 fine; Mrs. Aikman—$25 fine.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8370) Injunction issued.
[2] (8343, 8347) Prosecution contested.

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[1] (8370) Injunction issued.

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U.S. GOVERNMENT PRINTING OFFICE: 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8381–8440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *July 14, 1966.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

8381. (F.D.C. No. 51046. S. Nos. 65–381/4 A, 16–916 B.)

INFORMATION FILED: 4–15–65, S. Dist. Calif., against **Leonard Webb and Betty Webb, Los Angeles, Calif.**

CHARGE: Between 8–26–64 and 1–20–65, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty by Leonard Webb to 3 counts; by Betty Webb to 2 counts.

DISPOSITION: 8–2–65. Leonard Webb—3 years' imprisonment; and Betty Webb—2 years' imprisonment, suspended, and probation for 3 years.

8382. (F.D.C. No. 51324. S. Nos. 35–330 A, 108–641/9 A.)

INFORMATION FILED: 8–10–65, W. Dist. Ky., against **Trover Clinic, Inc., a corporation, t/a Clinic Pharmacy, and Arnold Thomas (pharmacist), Madisonville, Ky.**

CHARGE: Between 7–17–64 and 9–22–64, *amphetamine sulfate tablets* were dispensed 3 times, *Librium Hydrochloride capsules* were dispensed 5 times, and *thyroid tablets* were dispensed twice without prescriptions.

PLEA: Guilty by Thomas on 3 counts; nolo contendere by Trover Clinic, Inc., on 10 counts.

DISPOSITION: 9–13–65. Corporation—$1,000 fine; Thomas—$300 fine.

8383. (F.D.C. No. 51234. S. Nos. 1–129/31 A, 1–133/4 A, 1–136 A, 5–964 A, 5–966 A.)

INFORMATION FILED: 7–9–65, E. Dist. S.C., against **Robert Earl Andrews and Kenneth Donnell Lambert, Charleston Heights, S.C.**

CHARGE: Between 7–23–64 and 8–27–64, *amphetamine sulfate tablets* were dispensed 5 times and *dextro-amphetamine sulfate tablets* were dispensed 3 times without prescriptions.

PLEA: Guilty.

DISPOSITION: 9–21–65. Andrews—2 years in jail and 5 years on probation to begin at the termination of the jail sentence; Lambert—1 year in jail and 5 years on probation to begin at the termination of the jail sentence.

8384. (F.D.C. No. 51236. S. Nos. 1–152 A, 1–159 A.)

INFORMATION FILED: 7–9–65, E. Dist. S.C., against **Monroe Mathews Beach, Charleston Heights, S.C.**

CHARGE: Between 10–2–64 and 11–3–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–21–65. Probation for 3 years.

8385. (F.D.C. No. 51359. S. Nos. 96–691 A, 97–081 A.)

INFORMATION FILED: 9–3–65, S. Dist. Calif., against **Alfred C. Bauers, Malaga, Calif.**

CHARGE: Between 3–18–64 and 4–7–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–11–65. Two years in prison suspended and probation for 1 year.

8386. (F.D.C. No. 51552. S. Nos. 21–781/2 B.)

INDICTMENT RETURNED: 9–9–65, S. Dist. Tex., against **Samuel Gonzalez (taxi driver), Laredo, Tex.**

CHARGE: Between 1–28–65 and 2–12–65, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–30–65. Imprisonment for 6 months suspended, $100 fine and probation for 5 years.

8387. (F.D.C. No. 51327. S. Nos. 124–925/7 A, 124–937 A, 142–704 A.)

INFORMATION FILED: 7–27–65, Dist. N.J., against **Donald Cavanaugh, t/a Bon-Nod Milk Bar, Still Valley, N.J.**

CHARGE: Between 11–3–64 and 12–29–64, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–15–65. $5,000 fine, 1 year imprisonment suspended, and 5 years' probation.

8388. (F.D.C. No. 51352. S. Nos. 13–801/2 B.)

INFORMATION FILED: 8–9–65, Dist. N. Mex., against **George M. Madlock, Las Cruces, N. Mex.**

CHARGE: Between 1–29–65 and 2–1–65, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–19–65. Probation for 4 years.

8389. (F.D.C. No. 51604. S. Nos. 93–735/7 A.)

INFORMATION FILED: 10–5–65, E. Dist. Ark., against **Homer D. Church, Paragould, Ark.**

CHARGE: Between 12–16–64 and 12–17–64, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–19–65. $500 fine.

8390. (F.D.C. No. 51603. S. Nos. 25–421/2 B, 93–721/2 B.)

INFORMATION FILED: 10–5–65, E. Dist. Ark., against **Jimmy Church, Paragould, Ark.**

CHARGE: Between 7–29–64 and 1–23–65, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–19–65. $750 fine.

8391. (F.D.C. No. 50820. S. Nos. 70–421 V, 30–722 A, 30–727/8 A, 30–734 A, 30–736 A.)

INFORMATION FILED: 6–2–65, M. Dist. N.C., against **Oscar Beaver, John A. Spillman, Mocksville, N.C., and H. L. Key, Charlotte, N.C.**

CHARGE: Between 2–13–63 and 4–11–64, *amphetamine sulfate tablets* were dispensed 4 times and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Key to 1 count; by Spillman to 3 counts; by Beaver to 4 counts.

DISPOSITION: 10–21–65. Key—1 year in jail suspended and probation for 5 years; Spillman—2 years 6 months in jail, of which 2 years were suspended, and probation for 5 years; Beaver—1 year 6 months in prison, 1 year of which was suspended, and probation for 5 years.

8392. (F.D.C. No. 50821. S. Nos. 2–771 X, 2–780 X, 2–793/4 X, 508/9 X.)

INFORMATION FILED: 6–2–65, M. Dist. N. C., against **Hassel L. Key, Derita, N.C., Clifford Triplett, Staunton, Va., and Augustus Charles Cupeto, Newark, Del.**

CHARGE: Between 9–25–63 and 11–14–63, *amphetamine sulfate tablets* were dispensed 4 times and *amphetamine sulfate with thyroid tablets* were dispensed twice without a prescription.

PLEA: Guilty by Key to 2 counts; by Triplett to 3 counts; by Cupeto to 3 counts.

DISPOSITION: 10–21–65. Key—imprisonment for 2 years suspended, and probation for 5 years; Triplett—imprisonment for 2 years and 9 months of which 2 years were suspended, and probation for 5 years; Cupeto—imprisonment for 3 years of which 2 years were suspended, and probation for 5 years.

8393. (F.D.C. No. 51329. S. Nos. 156–829/31 A.)

INDICTMENT RETURNED: 9–9–65, S. Dist. Tex., against **Ted Mazoch (operator of a truck stop), Sealy, Tex.**

CHARGE: Between 12–12–64 and 12–16–64, *amphetamine sulfate tablets* were dispensed once and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–22–65. 1 year in prison suspended, 30 days in prison to be served and probation for 5 years.

8394. (F.D.C. No. 50368. S. No. 1–920 X.)

INDICTMENT RETURNED: 3–8–65, N. Dist. Ga., against **Larry Blackburn (employee of a service station), Gainesville, Ga.**

CHARGE: On 7–29–63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–28–65. Sentence of 1 year suspended and placed on probation for 2 years.

8395. (F.D.C. No. 51600. S. Nos. 34–347/8 A.)

INFORMATION FILED: 10–22–65, W. Dist. Ky., against **Carlos Leon Johnson (operator of Cross Roads Truck Stop), Park City, Ky.**

CHARGE: Between 9–2–64 and 9–21–64, *amphetamine sulfate tablets* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–8–65. $500 fine, plus costs.

8396. (F.D.C. No. 50806. S. Nos. 62–023/4 A.)

INFORMATION FILED: 9–3–65, S. Dist. Calif., against **Hardy D. Jones and George W. Franz, Los Angeles, Calif.**

CHARGE: On 2–7–64 and 2–18–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Jones to 2 counts; by Franz to 1 count.

DISPOSITION: 11–8–65. Jones—2 years' imprisonment suspended, and probation for 5 years; Franz—$250 fine.

8397. (F.D.C. No. 51338. S. Nos. 37–531/2 A.)

INFORMATION FILED: 8–10–65, N. Dist. Tex., against **Carroll Fleming, Fort Worth, Tex.**

CHARGE: Between 3–24–64 and 4–14–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–11–65. Six months in prison.

8398. (F.D.C. No. 51217. S. Nos. 33–148/51 A.)

INFORMATION FILED: 10–8–65, E. Dist. Tenn., against **James Patton Cleek, Gate City, Va.**

CHARGE: On 8–23–64, *amphetamine sulfate tablets*, *dextro-amphetamine sulfate tablets*, and *Biphetamine 20 capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–2–65. 270 days in prison and 2 years' probation.

8399. (F.D.C. No. 51029. S. Nos. 24–110/11 X.)

INFORMATION FILED: 2–3–65, N. Dist. Ohio, against **John Kirk, t/a Red's Sinclair Service, Streetsboro, Ohio.**

CHARGE: On 8–15–63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12–3–65. $1,000 fine, suspended, and probation for 1 year.

8400. **(2 criminal actions).** (F.D.C. Nos. 51212, 51598. S. Nos. 25–429/30 B; 25–433 B, 25–435 B.)

INFORMATIONS FILED: 3–30–65 and 9–1–65, E. Dist. Mo., against **Doyle Nance, Paragould, Ark., and Boyd Curtis, t/a Curtis Oil Co., Hayti, Mo.**

CHARGE: March 30th Information: on 3–3–65, *amphetamine sulfate tablets* were caused to be dispensed once by both defendants at Hayti, Mo., without a prescription.

September 1st Information: on 4–1–65, *amphetamine sulfate tablets* were caused to be dispensed once by both defendants at Hayti, Mo., without a prescription.

PLEA: Guilty.

DISPOSITION: 12–9–65. Nance—imprisonment for 2 years suspended, $500 fine, and probation for 3 years; Curtis—imprisonment for 2 years suspended, $2,000 fine, and probation for 3 years.

8401. (F.D.C. No. 51237. S. Nos. 108–629/36 A, 108–638/40 A, 109–143/49 A, 109–179/80 A.)

INFORMATION FILED: 8–19–65, S. Dist. Ind., against **Charles E. Moehlenkamp, M.D., Evansville, Ind.**

CHARGE: Between 7–22–64 and 9–17–64, *amphetamine sulfate tablets* were dispensed 20 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–22–65. $6,000 fine.

8402. (F.D.C. Nos. 48178; 50646. S. Nos. 4–670/3 X, 7–285 A.)

INFORMATION FILED: 10–28–64, W. Dist. Va., against **O. C. Davidson, t/a Cloyds Mountain Truck Stop, Dublin, Va.**

ALLEGED VIOLATION: Between 12–5–63 and 1–17–64, *red enteric-coated 10 mg. amphetamine sulfate tablets, white 5 mg. amphetamine sulfate tablets, green enteric-coated 10 mg. amphetamine sulfate tablets, 10 mg. dextro-amphetamine sulfate capsules,* and *phenobarbital sodium tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: On 11–20–64, the court sentenced the defendant to imprisonment for 15 months concurrent with a similar sentence also imposed on 11–20–64, for violation of probation. The defendant had violated the probation imposed in a previous action (see Drug and Device Notice of Judgment No. 7322).

8403. (F.D.C. No. 50018. S. Nos. 1–922/3 X.)

INFORMATION FILED: 9–29–64, N. Dist. Ga., against **Clyde Willard Dyer, Gainesville, Ga.**

CHARGE: On 7–29–63, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–1–65. 6 months' imprisonment to run concurrently with sentence of 12 months' imprisonment for violation of a State law.

8404. (F.D.C. No. 51325. S. Nos. 34–301/3 A.)

INFORMATION FILED: 8–9–65, W. Dist. Ky., against **George Armstrong, Louisville, Ky.**

CHARGE: Between 3–6–64 and 3–18–64, *dextro-amphetamine sulfate capsules* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–11–65. $200 fine, 6 months' imprisonment suspended, and probation for 2 years.

8405. (F.D.C. No. 51586. S. Nos. 4–231/4 B.)

INFORMATION FILED: 10–8–65, E. Dist. Tenn., against **Evert Liston Pack, Newport, Tenn.**

CHARGE: Between 2–13–65 and 2–20–65, *dextro-amphetamine sulfate capsules* were dispensed twice, *amphetamine sulfate tablets* were dispensed once, and *phenobarbital, amphetamine sulfate and thyroid tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–15–65. 4 years in prison suspended and probation for 4 years.

8406. (F.D.C. No. 51581. S. Nos. 32–748/52 A, 3–162 B.)

INFORMATION FILED: 10–8–65, E. Dist. Tenn., against **Marcella Marie Dalton and Edith Coffey, Del Rio, Tenn.**

CHARGE: Between 12–14–64 and 1–11–65, *dextro-amphetamine sulfate capsules* were dispensed 6 times without a prescription.

PLEA: Guilty by Dalton to 5 counts; by Coffey to 1 count.

DISPOSITION: 11–23–65. Dalton—210 days in prison; Coffey—90 days in prison.

8407. (F.D.C. No. 51567. S. Nos. 30–585 A, 30–597 A, 30–600 A, 109–639 A, 129–705/6 A, 129–715/16 A.)

INFORMATION FILED: 10–8–65, E. Dist. Tenn., against **Carl C. Frazier, t/a Halfway Truck Stop, Helen Hickman Daniels, Mary Francis Brown, and Georgia Williams (employees), Del Rio, Tenn.**

CHARGE: Between 10–26–64 and 12–4–64, *dextro-amphetamine sulfate capsules* were dispensed 8 times without a prescription.

PLEA: Guilty by Frazier to 8 counts; by Daniels to 3 counts; by Williams to 3 counts; and by Brown to 2 counts.

DISPOSITION: 11–23–65. Frazier—8 years in prison; Daniels—probation for 2 years; Williams—30 days in prison; and Brown—60 days in prison.

8408. (F.D.C. No. 51608. S. No. 34–656 B.)

INFORMATION FILED: 11–8–65, N. Dist. Ind., against **L. Gray Paddock, Fort Wayne, Ind.**

CHARGE: On 3–4–65, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–21–65. $1,000 fine, and probation for 6 months.

8409. (F.D.C. No. 51333. S. Nos. 30–975 A, 1–681 B.)

INFORMATION FILED: 11–15–65, E. Dist. Tenn., against **Eugene Tarlton, Wadesboro, N.C.**

CHARGE: Between 12–23–64 and 1–5–65, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–10–66. Probation for 3 years.

8410. (F.D.C. No. 51331. S. Nos. 32–019 A, 34–943 A, 34–946/8 A, 108–669/71 A.)

INDICTMENT RETURNED: 10–25–65, W. Dist. Ky., against **Herschel G. Compton, t/a Compton Rexall Drugs, Barlow, Ky.**

CHARGE: Between 9–23–64 and 11–4–64, *Librium Hydrochloride capsules* were dispensed 4 times, *Equanil tablets* were dispensed twice, *thyroid tablets* were dispensed once, and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–27–65. $800 fine.

8411. (F.D.C. No. 51551. S. Nos. 109–101 A, 109–105 A, 109–107/12 A, 109–125/8 A, 109–130/1 A.)

INFORMATION FILED: 10–22–65, W. Dist. Ky., against **Ely Drugs, Inc., Kenneth D. Calvert (vice president), Charles F. Brake (secretary-treasurer), and Charles W. Bunnell (pharmacist), Glasgow, Ky.**

CHARGE: Between 9–4–64 and 11–4–64, *Librium Hydrochloride capsules* were dispensed 6 times, *Equanil tablets* were dispensed 3 times, *thyroid tablets* were dispensed 4 times, and *prednisone tablets* were dispensed once without a prescription.

PLEA: Guilty by the corporation to 14 counts; by Calvert to 3 counts; by Brake to 3 counts; and by Bunnell to 4 counts.

DISPOSITION: 11–2–65. Corporation—$1,400 fine; Calvert—$300 fine suspended, and placed on probation for 6 months; Brake—$300 fine suspended, and placed on probation for 6 months; Bunnell—$400 fine suspended, and placed on probation for 6 months.

8412. (F.D.C. No. 51317. S. Nos. 109–221/3 A, 109–227 A.)

INFORMATION FILED: 11–8–65, E. Dist. Ky., against **Guy Tracy Noe (partner in the partnership of Green Mill Pharmacy), and Harold L. Hurst (employee), Harlan, Ky.**

CHARGE: Between 8–5–64 and 8–17–64, *Librium Hydrochloride capsules* were dispensed twice, and *prednisone tablets* were dispensed twice without a prescription.

PLEA: Guilty by each defendant.

DISPOSITION: 11–8–65. Noe—$400 fine, plus costs; Hurst—$400 fine, plus costs.

8413. (F.D.C. No. 51584. S. Nos. 30–792 A, 30–794/5 A, 30–797/800 A, 35–081/2 A.)

INFORMATION FILED: 10–29–65, S. Dist. Ohio, against **Charles V. Schwallie, t/a Schwallie's Pharmacy, and Maurice Moore (pharmacists), Cincinnati, Ohio.**

CHARGE: Between 9–22–64 and 12–15–64, *Librium Hydrochloride capsules* were dispensed 4 times, *Compazine tablets* were dispensed twice, *Trilafon tablets* were dispensed twice, and *Butisol Sodium tablets* were dispensed once without a prescription.

PLEA: Guilty by Schwallie to 9 counts; by Moore to 4 counts.

DISPOSITION: 11–18–65. Schwallie—$900 fine, of which $800 was suspended, and 6 months' probation; Moore—6 months' probation.

8414. (F.D.C. No. 51315. S. Nos. 33–662 A, 33–665/6 A, 33–668/9 A, 33–671 A, 33–673/4 A.)

INFORMATION FILED: 7–13–65, E. Dist. Ky., against **Welma B. DeHart (pharmacist), and Ernest R. DeHart, Olive Hill, Ky.**

CHARGE: Between 7–17–64 and 8–18–64, *Librium Hydrochloride capsules, reserpine tablets* and *Meticorten tablets* were each dispensed twice, and *thyroid tablets* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty by Welma DeHart to 8 counts; by Ernest DeHart to 3 counts.

DISPOSITION: 12–9–65. Welma DeHart—$1,600 fine, plus court costs; Ernest DeHart—$600 fine, plus court costs.

8415. (F.D.C. No. 50032. S. Nos. 70–421/27 X.)

INFORMATION FILED: 8–7–64, E. Dist. Tex., against **John C. Rogers Drug Store (a partnership), James G. Rogers and Edward N. Rogers (partners), and John L. Durham (pharmacist), Center, Tex.**

CHARGE: Between 10–30–63 and 11–13–63, *meprobamate tablets* were dispensed 3 times, *penicillin tablets* and *triamcinolone tablets* were each dispensed twice without a prescription.

PLEA: Guilty by the partnership to all 7 counts of the information; by James G. Rogers to 2 counts; by E. N. Rogers to 1 count; and by Durham to 4 counts.

DISPOSITION: 8–31–64. Partnership—$175 fine; J. G. Rogers—$50 fine suspended; and E. N. Rogers—$25 fine suspended. 3–18–65. Durham—$100 fine suspended.

8416. (F.D.C. No. 50454. S. Nos. 40–341/2 A, 40–344 A, 40–347/8 A.)

INFORMATION FILED: 10–19–64, N. Dist. Okla., against **Koronis Drug Store (a partnership), Picher, Okla., and Jimmie N. Koronis (pharmacist).**

CHARGE: Between 3–10–64 and 3–24–64, *meprobamate tablets* were dispensed 3 times and *penicillin tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–24–64. Partnership—$500 fine, of which $400 was suspended; individual—probation for 1 year.

8417. (F.D.C. No. 51035. S. Nos. 38–172 A, 39–622/7 A, 40–625 A, 40–637/40 A.)

INFORMATION FILED: 3–15–65, E. Dist. Tex., against **Thweat L. Hilliard, t/a Hilliard's Jacksonville Drug, and Ennis Canady (clerk), Jacksonville, Tex.**

CHARGE: Between 5–15–64 and 6–11–64, *meprobamate tablets* were dispensed 9 times, *triamcinolone tablets*, *penicillin tablets*, and *pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty to 12 counts by Hilliard; guilty to 5 counts by Canady.

DISPOSITION: 5–10–65. Hilliard—$600 fine. 4–29–65. Canady—$400 fine.

8418. (F.D.C. No. 49533. S. Nos. 37–003/11 V.)

INFORMATION FILED: 3–2–64, N. Dist. Ala., against **John D. McCutcheon, t/a North Highland Drug Co., Birmingham, Ala.**

CHARGE: Between 2–6–63 and 2–14–63, *methamphetamine hydrochloride tablets*, *amphetamine sulfate tablets*, and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were each dispensed twice, and *desoxyephedrine hydrochloride tablets*, *dextro-amphetamine sulfate tablets*, and *tablets containing a mixture of dextro-amphetamine sulfate and amobarbital* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 5–25–64. $750 fine, and probation for 3 years.

8419. (F.D.C. No. 50622. S. Nos. 54–727 A, 56–606 A.)

INFORMATION FILED: 12–11–64, S. Dist. Iowa, against **Dean G. Hume, D.O., Des Moines, Iowa.**

CHARGE: Between 2–21–64 and 5–12–64, *methamphetamine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3–5–65. Imprisonment for 6 months, $2,000 fine, plus costs.

8420. (F.D.C. No. 51051. S. Nos. 31–663/69 A, 31–671/74 A.)

INFORMATION FILED: 4–28–65, S. Dist. Ind., against **William J. Warn, M.D., Milan, Ind.**

CHARGE: Between 3–6–64 and 7–23–64, *methamphetamine hydrochloride tablets* were dispensed 5 times and *dextro-methamphetamine hydrochloride tablets* were dispensed 6 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–19–65. 6 months' jail sentence suspended, probation for 6 months, and $1,500 fine.

8421. (F.D.C. No. 50460. S. Nos. 73–102 A, 73–104 A, 73–106/7 A.)

INFORMATION FILED: 10–29–64, N. Dist. Ala., against **Waldo S. Elliott, t/a Elliott's Sinclair Truck Stop, Birmingham, Ala.**

CHARGE: Between 1–10–64 and 2–5–64, *methamphetamine hydrochloride tablets* were dispensed 4 times without prescriptions.

PLEA: Guilty.

DISPOSITION: 6–21–65. Sentence of 1 year and 1 day in jail suspended, 2 years' probation and $500 fine.

8422. (F.D.C. No. 50641. S. Nos. 96–972 X, 12–575 A, 12–577 A, 13–691/5 A.)

INFORMATION FILED: 4–2–65, Dist. Mass., against **Robert E. Sims, t/a Sims Drug Store, Springfield, Mass.**

CHARGE: Between 12–26–63 and 3–5–64, *Miltown tablets* were dispensed 6 times, and *Dexedrine Spansule capsules* were dispensed twice upon request for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–7–65. $500 fine.

8423. (F.D.C. No. 51583. S. Nos. 73–424 A, 73–426/8 A, 73–431/3 A.)

INFORMATION FILED: 9–23–65, N. Dist. Miss., against **Herbert A. Weissinger, t/a Herbert's Drug Store, Louise, Miss.**

CHARGE: Between 9–21–64 and 12–10–64, *Miltown tablets* were dispensed 3 times, *Benzedrine Sulfate tablets* were dispensed once, *Librium Hydrochloride capsules* were dispensed twice, and *pentobarbital sodium capsules* were dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 11–12–65. $2,100 fine.

8424. **Supplement to notice of judgment on drugs and devices No. 7476.** (F.D.C. No. 47075. S. Nos. 67–044/8 R, 67–054/5 R, 67–057/9 R.)

Dugan Drug Stores, Inc., appealed its conviction to the Circuit Court of Appeals for the Fifth Circuit, and on 1–21–64, the court reversed the conviction handing down the following opinion:

BREITENSTEIN, *Circuit Judge*: "Appellant Dugan Drug Stores, Inc., along with its president and four employees, was charged in a 10-count information with violations of the Food, Drug and Cosmetic Act[1] by refilling prescriptions for a potentially harmful drug without authorization by the prescribing physician.[2] A jury trial resulted in the acquittal of the president and all employees except one who plead guilty, and the conviction of the company on all counts.

"The first claim is that the information is defective and the proof insufficient because the prescriptions were not bona fide prescriptions issued by a doctor in the course of treatment of a patient but instead were obtained by federal agents for the purpose of investigating the defendants. The record shows no physician-patient relationship in the issuance of the prescriptions.

"The validity of the original prescriptions is not material. The charge is that the prescriptions required authorization for a refill and were refilled with-

[1] 21 U.S.C. §§ 301–392.
[2] 21 U.S.C. § 353(b)(1)(B). Such acts are a misbranding within the meaning of 21 U.S.C. § 331(k).

out such authorization. The government has proceeded against the dispensers rather than the prescribers. The prescriptions were valid on their faces. Authorization for a refill would have been a complete defense. Cases relating to the liability of doctors are not in point.[3] The effect of the appellant's argument is that the government would be precluded from investigations such as were made unless it had some unhealthy agents in need of the prescribed drugs. The record shows that the agents did no more than present an opportunity for the violation of the Act by the sale of a prescribed drug without the necessary refill authorization. The issue relates to the unauthorized refill—not to the existence of any physician-patient relationship. The information is sufficient and the evidence is ample to sustain the conviction.

"Inconsistency in the verdicts is claimed because the jury acquitted the individuals and convicted the company. This has no bearing on the counts to which one of the individuals plead guilty. In any event the rule is that consistency in verdicts is not necessary.[4]

"Appellant urges that the trial court erred in overruling various objections and in not granting various motions for mistrial based on the improper conduct of the prosecuting attorney. Without detailing the charges of misconduct, it is enough to say that they relate to the accosting of witnesses, implied threats to witnesses, remarks in the presence of the jury relating to matters which occurred out of the presence of the jury, prejudicial statements in colloquies between counsel and between court and counsel, and improper closing argument which went outside the record and made groundless charges and unreasonable inferences. The justification of the conduct is that it was instigated by defense tactics and that it was not prejudicial because the evidence of guilt is overwhelming.

"It should be unnecessary to say again that in a criminal prosecution a United States attorney has a double burden—the obligation to conduct the government's case zealously and the obligation to try that case fairly and with due regard to the rights of the accused.[5] In the case at bar zeal overcame fairness.

"We are not impressed with the argument that the conduct of the prosecutor was caused by the conduct of defense counsel. A prosecutor should be immune to improper tactics. If he feels that his opponent has overstepped, the remedy is an appeal to the trial court—not in the adoption of unfair procedures. The sufficiency of the evidence to establish guilt does not cure the misconduct. It was aggravated and persistent with such a probable cumulative effect on the jury that it may not be disregarded as unprejudicial.[6]

"This disposition of the case makes it unnecessary to consider the other assigned errors.

"Reversed and remanded for a new trial."

On 3–24–64, an indictment was returned against the corporation, which on 6–11–64, pleaded nolo contendere to the charge of dispensing methylprednisolone tablets on 3–6–61, upon request for a prescription refill without obtaining authorization by the prescriber. The corporation was fined $1,000.

8425. (F.D.C. No. 51588. S. Nos. 14–228/30 A, 15–520 A, 16–105/7 A, 16–117/18 A, 17–129 A, 17–135 A.)

INFORMATION FILED: 10–11–65, Dist. Mass., against **Stanley's Medical Center, Inc., t/a Post Office Pharmacy, and Stanley J. Szlachetka, (president), Chicopee Falls, Mass.**

CHARGE: Between 10–30–64 and 12–23–64, *Dexedrine Sulfate tablets* were dispensed 4 times, and *Miltown tablets* were dispensed 3 times upon request for prescription refills, without obtaining authorization by the prescriber; *AM Plus*

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[3] E.g., *Webb* v. *United States*, 249 U.S. 96; *DeFreese* v. *United States*, 5 Cir., 270 F. 2d 730, certiorari denied 362 U.S. 944; *Brown* v. *United States*, 5 Cir., 250 F. 2d 745, certiorari denied 356 U.S. 938; *Nigro* v. *United States*, 8 Cir., 117 F. 2d 624.

[4] *Dunn* v. *United States*, 284 U.S. 390, 393–394; see also *United States* v. *Dotterweich*, 320 U.S. 277, 279.

[5] See *Berger* v. *United States*, 295 U.S. 78, 88; *Dunn* v. *United States*, 5 Cir., 307 F. 2d 883, 885–886; *Hanford* v. *United States*, 5 Cir., 249 F. 2d 295, 296.

[6] See *Berger* v. *United States*, *supra*, p. 89.

capsules were dispensed twice, and *Pondets troches* and *Librium Hydrochloride capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–13–65. Corporation—$1,000 fine; Szlachetka—$500 fine, and 2 years' probation.

8426. (F.D.C. No. 51556. S. Nos. 36–466 A, 36–468 A, 36–470/2 A.)

INFORMATION FILED: 10–22–65, W. Dist. Okla., against **Alwyn Lee Segell, t/a Professional Discount Pharmacy No. 1, and Donald Colbert (assistant pharmacist), Oklahoma City, Okla.**

CHARGE: Between 9–28–64 and 10–9–64, *Dexedrine Sulfate tablets* were dispensed 4 times and *secobarbital sodium capsules* were dispensed once upon request for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 11–8–65. Segell—$375 fine; Colbert—$100 fine.

8427. (F.D.C. No. 51337. S. Nos. 54–692 A, 54–694/5 A.)

INFORMATION FILED: 9–9–65, W. Dist. Mo., against **Emory L. Bradley, Jr., (employee of a pharmacy), St. Joseph, Mo.**

CHARGE: Between 2–27–64 and 4–27–64, *desoxyephedrine hydrochloride tablets* were dispensed once and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–18–65. 90 days in custody of Attorney General and 2 years' probation.

8428. (F.D.C. No. 50476. S. Nos. 30–681/2 A.)

INFORMATION FILED: 10–12–64, S. Dist. Ohio, against **Hubert James Packenius, Jr., Cincinnati, Ohio.**

CHARGE: Between 2–5–64 and 2–7–64, *desoxyephedrine hydrochloride with phenobarbital and thyroid tablets* and *dextro-amphetamine sulfate tablets were* each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–14–65. 1 year in prison suspended, $300 fine, and probation for 1 year.

8429. (F.D.C. No. 50456. S. Nos. 7–123/5 X, 7–663/8 X, 7–670 X.)

INFORMATION FILED: 1–25–65, Dist. Mass., against **Bra-Wey Pharmacy, Inc., East Braintree, Mass., and Frank Strasnick (president-treasurer) and Herman Cohen (pharmacist).**

CHARGE: Between 8–23–63 and 10–30–63, *secobarbital sodium capsules* were dispensed 3 times, and *meprobamate tablets* were dispensed 6 times upon requests for prescription refills without obtaining authorization by the prescriber and *Librium Hydrochloride capsules* were dispensed once without a prescription.

PLEA: Guilty by the corporation and Strasnick to 10 counts; by Cohen to 5 counts.

DISPOSITION: 8–25–65. Corporation—$1,000 fine; Strasnick—6 months in prison suspended, 2 years' probation and $500 fine; and Cohen—6 months in prison suspended, 2 years' probation and $250 fine.

8430. (F.D.C. No. 51054. S. No. 59-882 A.)

INFORMATION FILED: 5-25-65, W. Dist. Mo., against **William Andrew Johnson, Kansas City, Mo.**

CHARGE: On 6-29-64, *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-29-65. 1 year in prison.

8431. (F.D.C. No. 50822. S. Nos. 12-503 A, 12-507 A, 13-815/18 A, 15-501/2 A.)

INFORMATION FILED: 4-2-65, Dist. Mass., against **Grant Drug, Inc., and Louis R. Pacifico (treasurer), and Samuel Penta (pharmacist), East Boston, Mass.**

CHARGE: Between 1-29-64 and 8-5-64, *Butisol Sodium tablets* (counts 3, 4, 6, and 8) were dispensed 4 times and *Miltown tablets* (counts 1 and 2) were dispensed twice upon requests for prescription refills without authorization by the prescriber; and *AM Plus capsules* (counts 5 and 7) were dispensed twice without a prescription.

PLEA: Guilty by corporation and Pacifico to all counts; by Penta to counts 3, 4, 7 and 8.

DISPOSITION: 10-13-65. Corporation—$1,000 fine; Pacifico—imprisonment for 6 months suspended, $500 fine, and probation for 2 years; Penta—imprisonment for 6 months suspended, and probation for 1 year.

8432. (F.D.C. No. 50624. S. Nos. 8-764/7 X, 93-343/4 X, 93-346/8 X, 12-383/84 A.)

INFORMATION FILED: 4-2-65, Dist. Mass., against **Braddock Drug Co., a corporation, Boston, Mass., Hyman J. Krasnoo (president and treasurer), and Frederick A. Cohen (pharmacist).**

CHARGE: Between 11-18-63 and 1-8-64, *Butisol Sodium tablets* and *Dexedrine Sulfate tablets* were each dispensed 5 times upon requests for prescription refills without authorization by the prescriber, and *AM Plus capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6-7-65. Corporation—$200 fine; individuals—$100 fine each.

8433. (F.D.C. No. 51242. S. Nos. 37-568/72 A, 38-435 A, 38-437 A.)

INDICTMENT RETURNED: 9-17-65, N. Dist. Tex., against **Troy T. Sumpter, Rhome, Tex.**

CHARGE: Between 3-20-64 and 9-23-64, *Biphetamine 20 capsules* were dispensed 4 times, *amphetamine sulfate tablets* were dispensed once, *desoxyephedrine hydrochloride tablets* were dispensed once, and *Biphetamine-T 20 capsules* were dispensed once without prescription.

PLEA: Guilty.

DISPOSITION: 11-23-65. 6 years in prison.

8434. (F.D.C. No. 47120. S. Nos. 31-671 R, 32-196 R.)

INFORMATION FILED: 6-12-62, E. Dist. La., against **Ellis J. Jenkins (vice president of Rieger Pharmacies, Inc.), Baton Rouge, La.**

CHARGE: On 1-5-61, *Desoxyn Hydrochloride tablets* were dispensed once and on 1-6-61, *Diuril tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5-7-65. $500 fine.

8435. (F.D.C. No. 50472. S. Nos. 36–201/06 X.)

INFORMATION FILED: 10–6–64, N. Dist. Ala., against **Leonard B. Frederick, t/a Frederick's Truck Stop, Cottondale, Ala.**

CHARGE: On 10–6–63, *desoxyephedrine hydrochloride tablets* were dispensed 5 times and *amphetamine sulfate tablets* were dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 11–8–65. $1,000 fine, 1 year jail sentence suspended, and 3 years' probation.

8436. (F.D.C. No. 51361. S. Nos. 2–933 A, 2–936 A, 32–901/2 B, 33–142/3 B.)

INFORMATION FILED: 8–13–65, W. Dist. N.C., against **Richard F. Austraw, t/a Beverly Hills Pharmacy, Asheville, N.C.**

CHARGE: Between 12–8–64 and 1–19–65, *Equanil tablets* and *Dexedrine Sulfate tablets* were each dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–8–65. $1,000 fine, and probation for 3 years.

8437. (F.D.C. No. 51353. S. Nos. 75–421 A, 75–427/9 A, 75–433/5 A, 75–437 A.)

INFORMATION FILED: 8–30–65, N. Dist. Ala., against **Wood's Drug Store, Inc. (a corporation), William C. Wood (president), Elias S. Khalaf and Doyle Hanson (pharmacists), Birmingham, Ala.**

CHARGE: Between 5–26–64 and 10–20–64, *Fiorinal tablets* were dispensed 4 times without a prescription and *Equanil tablets* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9–23–65. Corporation—$200 fine; Wood—$100 fine; Khalaf—$100 fine; Hanson—$100 fine.

8438. (F.D.C. No. 51347. S. Nos. 33–159 A, 33–163 A, 33–166 A, 108–521 A, 109–241 A, 109–942 A.)

INFORMATION FILED: 8–16–65, E. Dist. Ky., against **James Edward Neal, Harlan, Ky.**

CHARGE: Between 8–10–64 and 10–6–64, *secobarbital sodium capsules* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–10–65. Three months in jail.

8439. (F.D.C. No. 50620. S. Nos. 72–921/2 A, 72–924 A, 72–992/6 A.)

INFORMATION FILED: 2–9–65, S. Dist. Miss., against **John Felix Miller, t/a Farish Street Drug Store, Jackson, Miss.**

CHARGE: Between 1–16–64 and 3–18–64, *Syndrox Methamphetamine Hydrochloride tablets* and *Dexedrine Sulfate tablets* were each dispensed twice, and *dextro-amphetamine sulfate tablets, Biphetamine 20 capsules, pentobarbital sodium capsules,* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–2–65. Imprisonment for 6 months suspended, probation for 6 months, and $200 fine.

8440. (F.D.C. No. 49150. S. Nos. 63–689/90, V, 63–693/6 V, 63–698/9 V.)

INFORMATION FILED: 11–9–63, S. Dist. Calif., against **Plato Pharmacy, Inc., Hollywood, Calif., Cleon F. Plato (president), and Arthur M. Gillespie (pharmacist).**

CHARGE: Between 3–29–63 and 4–18–63, *Thorazine tablets* (counts 2, 3, 6 and 7) were dispensed 4 times, *Metandren Linguets* (counts 4 and 8) were dispensed twice, and *Miltown tablets* (count 5) were dispensed once, without a prescription; and *Miltown tablets* (count 1) were also dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Nolo contendere by the corporation to all counts; by Plato to counts 1–5, and by Gillespie to counts 6–8.

DISPOSITION: 1–21–64. Corporation—$2,400 fine of which $2,100 was suspended; Plato—$500 fine of which $400 was suspended; and Gillespie—$300 fine suspended.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 8381 TO 8440

PRODUCTS

[1] (8402) Violation of probation.
[2] (8424) Prosecution contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8402) Violation of probation.

[1] (8402) Violation of probation.
[2] (8424) Prosecution contested. Contains opinion of the court.

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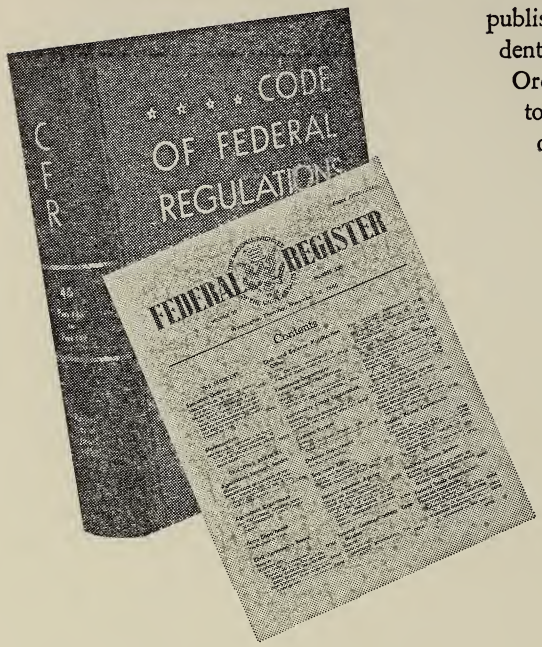

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D.D.N.J., F.D.C. 8441–8500 Issued July 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8441–8500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere; and (3) an injunction proceeding in which a decree of permanent injunction was entered. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*
WASHINGTON, D.C., *July 20, 1966.*

CONTENTS *

*For presence of a habit-forming substance without warning statement, see No. 8454; omission of, or unsatisfactory, ingredients statements, Nos. 8443, 8450, 8452, 8453; failure to bear a label containing an accurate statement of the quantity of the contents, No. 8450; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 8450, 8452, 8453, 8455; cosmetics actionable under the drug provisions of the Act, Nos. 8492–8494.

221–769—66——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8441–8500

Adulteration, Section 501(a)(2)(B), the article was a drug and the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice to assure that such drug met the requirements of the Act as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported and was represented to possess; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia, National Formulary), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man, and it contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(e)(1)(A)(i), the article was a drug, and its label failed to bear the established name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; 502(l), the article purported to be and was represented as a drug composed, in part, of an antibiotic drug and (1) was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507, or (2) such certificate or release was not in effect with respect to such drug; Section 503(b)(1), the article was a drug intended for use by man, which was a habit-forming drug to which Section 502(d) applied, or because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the

meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8441. Hydrocortisone acetate ophthalmic ointment and bacitracin ophthalmic ointment. (F.D.C. No. 50866. S. Nos. 8–096/7 A.)

QUANTITY: 528 cases, each containing 1 ⅛-oz. tube of *hydrocortisone acetate ophthalmic ointment*, and 576 cases, each containing 1 ⅛-oz. tube of *bacitracin ophthalmic ointment*, at Cumberland, Md.

SHIPPED: 7–23–64 (528-case lot) and 7–8–64 (576-case lot), from East Paterson, N.J., by Biocraft Laboratories, Inc.

LABEL IN PART: (Tube) "Hydrocortisone Acetate 0.5% with Neomycin Ophthalmic Ointment * * * Distributed by Cumberland Pharmacal Co. Cumberland, Md."; and "Bacitracin Ophthalmic Ointment * * * Distributed by Cumberland Pharmacal Co. Cumberland, Md."

RESULTS OF INVESTIGATION: Examination showed that the articles contained metal fragments. Inspection of Biocraft Laboratories, Inc., on 9–18/21–64, disclosed that the metal tubes in which the articles were packed contained metal fragments when received from the tube manufacturer and that Biocraft Laboratories, Inc., had attempted to remove such particles by use of a vacuum device which was designed only to remove lint.

LIBELED: 12–4–64, Dist. Md.

CHARGE: 501(a)(2)(B)—when shipped (both lots), the methods used in the facilities and controls used for the manufacture, processing, packing, and holding of the articles did not conform to and were not operated and administered in conformity with current good manufacturing practice to assure that the articles met the quality and purity characteristics which they purported and were represented to possess; 501(c)—(*hydrocortisone acetate ophthalmic ointment*) the purity and quality of the article fell below that which it was purported to possess; 501(b)—(*bacitracin ophthalmic ointment*) the article was represented as a drug, "Bacitracin Ointment," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the standard set forth in such compendium; and 502(j)—the articles were dangerous to health when used in the dosage and with the frequency and duration recommended and suggested in its labeling.

DISPOSITION: 1–8–65. Default—destruction.

8442. Ophtha PBN ophthalmic ointment. (F.D.C. No. 50863. S. No. 86–977 A.)

QUANTITY: 282 cases, each containing 1 tube, at Springfield, Mo.

SHIPPED: 7–23–64, from East Paterson, N.J., by Biocraft Laboratories, Inc.

LABEL IN PART: (Tube) "Ophtha PBN Ointment Ophthalmic Each gram contains: Hydrocortisone Acetate 15 mg. Neomycin Sulfate 5 mg. (Equivalent to 3.5 mg. Neomycin Base) * * * Caution * * * Usual Dosage * * * Manufactured * * * For Misemer Pharmaceuticals, Inc., Springfield, Mo. * * * Size: ⅛ Oz.–3.54 GM."

RESULTS OF INVESTIGATION: Analysis showed that the article contained essentially the declared amount of hydrocortisone acetate, and that the article contained metal fragments. Inspection of Biocraft Laboratories, Inc., on 9–18/

21–64, disclosed that the metal tubes in which the article was packed contained metal fragments when received from the tube manufacturer and that Biocraft Laboratories, Inc., had attempted to remove such particles by use of a vacuum device which was designed only to remove lint.

LIBELED: On or about 12–7–64, W. Dist. Mo.

CHARGE: 501(a)(2)(B)—when shipped, the methods used in and the facilities or controls used for the manufacture, processing, and packing of the article did not conform to and were not operated and administered in conformity with current good manufacturing practice to assure that the article met the quality and purity characteristics which the article purported and was represented to possess; 501(c)—the quality and purity of the article fell below that which it purported and was represented to possess: and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof.

DISPOSITION: 1–20–65. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

8443. Various antibiotic, sulfa and pentaerythritol tetranitrate drugs. (F.D.C. No. 48869. S. Nos. 38–556 T, 45–236 T, 56–617/18 T, 59–532/3 T, 67–701 T, 88–722 T, 46–270 V.)

INFORMATION FILED: 5–15–64, E. Dist. Mo., against Jamieson-McKames Pharmaceuticals, Inc., St. Louis, Mo.

SHIPPED: Between 3–10–61 and 8–20–62, from St. Louis, Mo., to Birmingham, Ala., Pocahontas, Ark., Austin, Tex., Waterloo, Ill., Detroit, Mich., and Coulterville, Ill.

LABEL IN PART: (Btl.) "1 Gallon (3735 cc.) Cyclonized Trisulfacidin Suspension Each Teaspoon (5 cc.) contains: Sulfamethazine—0.166 Gm. JAMIESON–McKAMES PHARMACEUTICALS, Inc. St. Louis 16, Mo.," (btl.) "500" [or "1000"] SULAMINE* PLUS Each Tablet Contains: SULFAMETHYLTHIADIAZOLE—250 Mg. METHENAMINE MANDELATE—250 Mg. PHENYLAZODIAMINE PYRIDINE—50 Mg. * * * JAMIESON-McKAMES PHARMACEUTICALS, INC. ST. LOUIS 16, MO.," (drum) "VASOFAC–80 [or "VASOFAC–80 WITH PHENOBARBITAL"] Each sustained release tablet contains: Pentaerythritol tetranitrate—80 mg. [or "Pentaerythritol tetranitrate—80 mg. Phenobarbital—45 mg."] Manufactured For PHARMAFAC INC. Austin, Texas Manufactured by JAMIESON-McKAMES, INC.," (btl.) "60 cc. CHERI-PENN [or "CHERI-PENN—S* with Sulfonamides"] Buffered Penicillin G. Powder * * * JAMIESON-McKAMES Pharmaceuticals, Inc. St. Louis 16, Mo.," and (btl.) "60 cc. 'G-CILLIN' Buffered Penicillin G Powder * * * Distributed by LAKEHURST PHARMACAL CO. Detroit 38, Michigan."

CHARGE: *Trisulfacidin suspension*, 501(d)(2)—when shipped, a product containing among its ingredients, sulfacetamide and no sulfamethazine, had been substituted for an article containing among its ingredients, sulfamethazine and no sulfacetamide, which the drug was represented to be; 502(a)—the labeling of the article was false and misleading since the labeling represented and suggested that the article contained sulfamethazine whereas it did not contain sulfamethazine; and 502(e)(2)—the label of the article failed to bear the

common or usual name of each active ingredient since the article contained the active ingredient, sulfacetamide, which was not declared on the label.

Sulamine tablets, *Vasofac-80 tablets*, and *Vasofac-80 with phenobarbital tablets*, 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drugs.

Cheri-Penn powder and *G-Cillin powder*, 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirements, since the lot number on the label of each drug was not a lot number from which it was possible to determine the complete manufacturing history of the package of the drug as required by regulations, in that such lot number did not represent a homogeneous lot; and 502(l)—the articles were represented to be drugs composed of a kind of penicillin and were not from batches with respect to which a certificate or release had been issued pursuant to 507, and (*G-Cillin powder* only) since no certificate had been issued which was applicable to the article as labeled.

Cheri-Penn-S powder, 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since the lot number on the label of the article was not a lot number from which it was possible to determine the complete manufacturing history of the package of the drug as required by regulations, in that such lot number did not represent a homogeneous lot; 502(l)—the article was represented to be a drug composed in part of a kind of penicillin and it was from a batch with respect to which a certificate was not effective, since the certificate issued was obtained by misrepresentation of the material fact that the lot number did not apply to a homogeneous batch.

PLEA: Guilty.

DISPOSITION: 11–6–64. $1,000 fine.

8444. **Pan-Zyme tablets and Centalone tablets.** (F.D.C. No. 50657. S. Nos. 103–299/300 A.)

QUANTITY: 54 250-tablet btls. of *Pan-Zyme* and 3 100-tablet btls. of *Centalone*, at Seattle, Wash.

SHIPPED: 8–14–64 and 9–3–64, from Bothell, Wash., by Medical & Biological Research Laboratories, Inc., to Portland, Oreg., and subsequently returned to Seattle, Wash.

LABEL IN PART: (Btl.) "Pan-Zyme Gastro-Enteric Enzyme Compound Each tablet contains: Proteolytic potency equiv. to Pancreatin, N.F. 0.372 gm. Amylolytic potency equiv. to Pancreatin, N.F. 0.276 gm. * * * Peptic Potency equiv. to Pepsin N.F. 0.009 gm. Ox bile (dessicated) 0.056 gm. * * * Suggested adult dose:" and "Centalone (Steroid extract of normal human placentae) For use in rheumatoid arthritis and related collagen diseases. Each tablet is equivalent to 5 micrograms of 17,21-dihydroxy-20-ketosteroids Dosage: 1 to 4 tablets daily * * * see brochure Medical & Biological Research Laboratories, Inc. * * * Bothell, Washington."

LIBELED: On or about 10–5–64, W. Dist. Wash.

CHARGE: *Centalone*, 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

Pan-Zyme, 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement, since its labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling; and 503(b)(4)—the article was subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–9–64. Default—destruction.

8445. **Quell Sippy Dietary.** (F.D.C. No. 50213. S. No. 32–439 A.)

QUANTITY: 35 cases, 24 6-oz. cans each, and 14 6-oz. cans, at Cincinnati, Ohio.

SHIPPED: Between 2–25–64 and 5–19–64, from Evansville, Ind., by Mead Johnson Laboratories.

LABEL IN PART: (Can) "Quell Modified Sippy Dietary Mead Johnson Laboratories, a division of Mead Johnson & Company Evansville 21, Indiana."

LIBELED: 5–26–64, S. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug; and 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use, and adequate directions for use for the diagnosis and treatment of ulcers for the layman cannot be written.

DISPOSITION: 11–5–64. Default—destruction.

8446. **Surgident's Predlon Kit.** (F.D.C. No. 50714. S. Nos. 9–235 A, 9–327 A.)

QUANTITY: 22 ctns., each containing 6 pkgs., and 72 pkgs., at Richmond, Va.

SHIPPED: Between 6–4–64 and 10–15–64, from Los Angeles, Calif., by Surgident, Ltd.

LABEL IN PART: (Pkg.) "Surgident's Predlon Kit Dental Suspension Topical A Post Operative Control of Hypersensitivity in Dentine and Pulp Treatment of Pulpal Irritation Distributed by Surgident, Ltd., Los Angeles, California * * * Each CC. Predlon Suspension Contains 5 Mg. Prednisolone Acetate, 100 MG. Sulfacetamide Sodium * * * Caution: For Dentist's Use Only. Federal law prohibits dispensing without prescription. Read Package insert before use."

RESULTS OF INVESTIGATION: Analysis of one lot showed that the article contained the declared amount of sodium sulfacetamide, and that the prednisolone acetate was 136 percent of the declared amount.

LIBELED: 11–19–64, E. Dist. Va.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 12–23–64. Default—destruction.

DRUG FOR VETERINARY USE

8447. Phenylbutazone injectable. (F.D.C. No. 50427. S. No. 2–063 A.)

QUANTITY: 12 60-cc. vials at Opa-locka, Fla.

SHIPPED: 7–9–64, from Hamilton, Canada, by Delta Sales.

LABEL IN PART: (Vial) "Phenylbutazone Injectable Each cc. contains: Phenylbutazone (as the Sodium Salt) 200 mg. * * * For Veterinary Use Only * * * Delta Sales Hamilton, Canada."

LIBELED: 8–5–64, S. Dist. Fla.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 11–19–64. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED*

8448. Penicillin G, procaine, Isojects. (F.D.C. No. 50747. S. No. 42–667 A.)

QUANTITY: 401 syringes, each containing 1,200,000 units of penicillin, at Lakewood, Colo., in possession of Medical Service Pharmacy.

SHIPPED: On or about December 1963, from Dallas, Tex.

LABEL IN PART: (Syringe) "Penicillin G Procaine * * * Isoject * * * NY NY * * * Exp. Date 10/64."

ACCOMPANYING LABELING: Insert entitled "Disposable Syringe Penicillin G Procaine Isoject."

LIBELED: 11–25–64, Dist. Colo.

CHARGE: 502(l)—while held for sale, the article purported to be a drug composed wholly or in part of a kind of penicillin, and it was not from a batch with respect to which a certificate or release issued pursuant to law was in effect.

DISPOSITION: 1–6–65. Default—destruction.

8449. Tokisan. (F.D.C. No. 50881. S. No. 84–065 A.)

QUANTITY: 334 ½-oz. btls. at Santurce, P.R.

SHIPPED: 4–9–64, from Coral Gables, Fla., by Lavall Products, Inc.

LABEL IN PART: (Btl. and ctn.) "Tokisan * * * Each 100 cc contains: Benzocaine 500 mg. Tyrothricin 30 mg. Benzalkonium Chloride 1:5000 Phenylephrine HCl 0.25% Sorbitol 37.5 Gm. * * * Manufactured for Lavall Products, Inc. * * * Coral Gables 34 Florida."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 71 percent of the declared amount of tyrothricin.

LIBELED: 12–29–64, Dist. P.R.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Each 100 cc contains: * * * Tyrothricin 30 mg." was false and misleading; and 502(l)(1)—the article purported and was represented as a drug composed in part of an antibiotic drug, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: 2–15–65. Default—destruction.

*See also No. 8443.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8450. Dextro-amphetamine sulfate tablets and other amphetamine products. (F.D.C. No. 50383. S. Nos. 15-683/7 X.)

INFORMATION FILED: 10-6-64, S. Dist. Ohio, against Jerry Anderson, truck driver, Kernersville, N.C., and Lois Hamilton, truck stop employee, Henderson, W. Va.

ALLEGED VIOLATIONS: On 9-14-63, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Gallipolis, Ohio, after shipment in interstate commerce, the defendants caused the tablets to be dispensed in unlabeled plastic bags, which act resulted in the tablets being misbranded (count 1).

Between 9-14-63 and 9-20-63, the defendants caused to be delivered for introduction into interstate commerce, at Gallipolis, Ohio, for transportation into the State of Kentucky, unlabeled bags containing tablets which contained, among other ingredients, amphetamine sulfate (counts 2, 5), which tablets were misbranded, and unlabeled bags containing capsules of dextro-amphetamine sulfate (counts 3, 4), which capsules were misbranded.

CHARGE: *Dextro-amphetamine sulfate tablets*, 503(b)(1)—while held for sale, the article was a drug within the meaning of 503(b)(1)(B), and was dispensed without a prescription from a practitioner licensed by law to administer the drug.

The other articles, 502(b)(1) and (2)—when shipped, the articles were in package form, and failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of contents; 502(e)(1)(A)(i)—the label of the article failed to bear the established name of the drug; 502(f)(1)—the labeling failed to bear adequate directions for use; and 503(b)(1)—the articles were drugs within the meaning of 503(b)(1)(B), and were dispensed without a prescription from a practitioner licensed by law to administer the drugs.

PLEA: Guilty by Anderson to counts 1, 2, 3, 4, and 5; and by Hamilton to counts 1, 2, and 3.

DISPOSITION: 1-14-65. Anderson—imprisonment for 1½ years, 1 year of which was suspended, and probation for 1 year; Hamilton—1 year's imprisonment suspended, and probation for 1 year.

8451. Various prescription drugs. (F.D.C. No. 50613. S. Nos. 4-921 X, 4-945 X, 42-633/5 X, 42-797/9 X, 54-027/9 X.)

INFORMATION FILED: 11-30-64, Dist. N.J., against Robert Brinton Morris, t/a Robert Brinton Morris Laboratories, and as Uno Laboratories, Wenonah, N.J.

SHIPPED: Between 5-22-63 and 10-22-63, from Wenonah, N.J., to Washington, D.C., Maryland Park, Md., Southampton, Pa., and Holland, Pa.

LABEL IN PART: (Btl.) "SODIUM PENTOBARBITAL TABLETS 1½ GR PER CAPSULE * * * CAUTION: * * * WARNING * * * MANUFACTURERS DISTRIBUTORS UNO LABORATORIES PITMAN, NEW JERSEY"; "RBM C. T. Gray No. 1 [or "White No. 2," or "Pink No. 3"] PRO-TABS (IMPROVED) Amphetamine Phosphate 5 mg. Thyroid 1 gr. Atropine Sulphate 1/360 gr. Aloin ¼ gr. [or "Amphetamine Phosphate 5 mg. Thyroid 1 gr. Atropine Sulphate 1/360 gr." or "Phenobarbital ¼ gr. Amphetamine Phosphate 5 mg. Thyroid 1 gr."] CAUTION: * * * Robert Brinton Morris Laboratories

Manufacturers Distributors PITMAN, NEW JERSEY"; "C. T. Yellow [or "YELLOW SINGLE SCORED."] Dextro-Amphetamine Sulphate 5 MGM TABLET"; "White Double Scored Amphetamine Sulphate 10 mg. per tablet"; "RBM PROFETAMINE PHOSPHATE (Brand of Racemic Amphetamine Phosphate) CHEWING GUM 10 MGM EACH"; APIOL ERGOT CAPSULES Each capsule contains: Ergot, powdered U.S.P. XII 259.2 mg. Aloin, U.S.P. 8.1 mg. Apiol Fluid Green 290 mg. Oil Pennyroyal 28 mg. Cottonseed Oil U.S.P. q.s. 10 minims"; and "TIMCAPS AMPHETAMINE O.B. COMP. ORANGE CLEAR [or "DEXTRO AMPHETAMINE SULFATE BROWN & CLEAR 15 mg."] (TIMED DISINTEGRATION CAPSULES) Each Capsule Contains: Phenobarbital ¼ gr. WARNING: * * * dl-Amphetamine Sulfate 15 mg. Thyroid 3 gr. Aloin ¼ gr. Atropine Sulfate 1/180 gr. * * * [or "Dextro-Amphetamine Sulfate 15 mg."]."

CHARGE: 502(f)(1)—when shipped, the labeling of the articles of drug failed to bear adequate directions for use and they were not exempt from this requirement, since they were shipped to persons not lawfully engaged in the manufacture, transportation, storage, distribution, or dispensing of prescription drugs; and 503(b)(1)—the articles were prescription drugs, and while held for sale by the defendant were dispensed without a prescription therefor, from a practitioner licensed by law to administer such drugs.

PLEA: Nolo contendere.

DISPOSITION: 4–2–65. Probation for 5 years.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

8452. **Various prescription drugs.** (F.D.C. No. 47546. S. Nos. 9–908/13 T, 11–064/78 T.)

QUANTITY: Undetermined numbers of btls. and other containers of various drugs, at Albany, N.Y., in possession of Cheris Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Professional Sample," "Complimentary," and "Physician's Sample."

RESULTS OF INVESTIGATION: Some of the articles had been repacked by the Cheris Pharmacy, and some of the articles had not been repacked.

LIBELED: 4–18–62, N. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Complimentary," "Physician's Sample," and similar wording borne on the labels of a number of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—a number of the articles were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement, since their labels failed to bear an identifying lot number as required by regulations; and 503(b)(4)—a number of the articles were drugs subject to the provisions of 503(b)(1), and their

*See also No. 8444.

labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: On 5–17–62, Cheris Pharmacy, Albany, N.Y., claimant, filed an answer denying that the articles were misbranded. Thereafter, the Government served written interrogatories upon the claimant. On 12–29–64, a decree of condemnation was entered and the articles were ordered destroyed.

8453. **Various prescription drugs.** (F.D.C. No. 46609. S. Nos. 30–402 T, 30–405/7 T.)

QUANTITY: Approximately 257 pkgs. and 111 repackaged containers of various prescription drugs, and 1 unlabeled 117-tablet btl. of *pentaerythritol tetranitrate*, at Los Angeles, Calif., in possession of H & S Drug Co.

SHIPPED: On unknown dates, from outside the State of California.

LABEL IN PART: (Some labels) "Physician's Sample," "Professional Sample," and "Clinical Supply Not To Be Sold."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer from physicians' samples into containers labeled with the brand names of the drugs; and some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs and which had not, at the time the article was libeled, been repacked by the dealer, and whose labels bore sample legends and the names and addresses of manufacturers, packers, or distributors located outside the State of California.

LIBELED: 11–6–61, S. Dist. Calif.

CHARGE: All the labeled articles, 502(a)—while held for sale, the words, "Physician's Sample," "Professional Sample," "Clinical Supply Not To Be Sold," and similar wording on the labels of the articles, were false and misleading as applied to those articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

Pentaerythritol tetranitrate tablets, 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the article failed to bear a label containing the common or usual name of the article; 502(f)(1)—the article failed to bear labeling containing adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and it failed to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–18–64. Default—destruction.

8454. **Aspasmol C.T. tablets.** (F.D.C. No. 50438. S. No. 51–823 A.)

QUANTITY: 4 cases, each containing 24 unlabeled 1,000-tablet btls., and 24 labeled and unlabeled 1,000-tablet btls., at Fort Wayne, Ind., in possession of International Food & Drug Corp. (formerly Gilroy/Mays Co., Inc.).

SHIPPED: 6–19–62, from Kalamazoo, Mich., by Kapco, Inc.

LABEL IN PART: (Btl.) "G&M 1000 Tablets Aspasmol C.T. Each Tablet contains Phenobarbital ¼ gr. Hyoscine Hydrobromide .0072 mg. Hyoscyamine Hydrobromide .128 mg. Atropine Sulfate .024 mg. Manufactured for Gilroy/Mays Co., Inc. Fort Wayne, Indiana."

RESULTS OF INVESTIGATION: The article was shipped in labeled shipping cartons containing unlabeled bottles. Some of the bottles were subsequently labeled by the dealer.

LIBELED: 8–7–64, N. Dist. Ind.

CHARGE: 502(d)—when shipped and while held for sale, the article was for use by man and it contained phenobarbital, a chemical derivative of barbituric acid, which had been, by regulations, designated as habit forming, and it failed to bear a label containing the statement "Warning—May be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since it failed to bear a label containing the recommended or usual dosage, and an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug; and 503(b)(4)—the article was a drug subject to 503(b)(1), and it failed to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–27–65. Consent—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

8455. Uriseptina tablets. (F.D.C. No. 50436. S. No. 84–040 A.)

QUANTITY: 50 1,000-tablet btls., at Santurce, P.R., in possession of Dianovin Pharmaceuticals, Inc.

SHIPPED: 2–26–64, from Long Island City, N.J.

LABEL IN PART: (Btl.) "Uriseptina * * * Cada Tableta Contiende Sulfacetamida 0.5 gms. Precaucion * * * Dianovin Pharmaceuticals, Inc. * * * Santurce, P.R."

RESULTS OF INVESTIGATION: The article was shipped in bulk and repacked by the dealer.

Analysis showed that the article contained approximately 90 percent of the declared amount of sulfacetamide. The National Formulary, an official compendium, requires that sulfacetamide tablets contain not less than 95 percent of the declared amount of sulfacetamide.

LIBELED: 10–5–64, Dist. P.R.

CHARGE: 501(b)—while held for sale, the strength of the article differed from the standard set forth in the National Formulary; 502(a)—the label statement "Sulfacetamida 0.5 gms." was false and misleading; 502(b)(1)—the firm name on the label was not that of the manufacturer and the name was not qualified by an appropriate phrase that expressed the facts; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes, and its labeling failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the drug.

DISPOSITION: 12–29–64. Default—destruction.

*See also Nos. 8443–8445, 8450–8454.

8456. Dipyrone injection. (F.D.C. No. 50441. S. No. 82–596 A.)

QUANTITY: 13 boxes, each containing 100 5-cc. ampuls and 1 box containing 60 5-cc. ampuls, at Brooklyn, N.Y., in possession of Gotham Pharmaceutical Co., Inc.

SHIPPED: The article was manufactured in part by the dealer from bulk dipyrone powder shipped 12–1–61, from Japan.

LABEL IN PART: (Box) "Dipyrone 2.5 Gm. per 5 cc. Each 5 cc. contains Dipyrone (Phenyldimothylpyrazolone methylaminomethane sodium sulfonate) 2.5 Gm. * * * Indications: For use as an analgesic, antipyretic, and antirheumatic. Dosage: * * * Caution * * * Caution: Federal law prohibits * * * Gotham Pharmaceutical Co., Inc., Brooklyn, N.Y." and (ampul) "Dipyrone 2.5 gm. per 5 cc. Intramuscular or Intravenous See box label Gotham Pharm. Co. Brooklyn, N.Y."

LIBELED: 8–13–64, E. Dist. N.Y.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 12–3–64. Consent—claimed by Gotham Pharmaceutical Co., Inc., for relabeling.

8457. Amphetamine tablets and capsules and barbiturate capsules. (F.D.C. No. 50281. S. Nos. 59–777/84 A.)

QUANTITY: 23,630 *amphetamine tablets*, 711 *amphetamine capsules*, and 46 *barbiturate capsules*, at Kansas City, Kans., in possession of A. G. Bonsignore, D.C.

SHIPPED: Prior to 6–4–64, from outside the State of Kansas.

LIBELED: 6–4–64, Dist. Kans.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt since they were in the possession of a person not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and were not to be dispensed as required by law.

DISPOSITION: 11–25–64. Default—destruction.

8458. Amphetamine tablets and capsules. (F.D.C. No. 50672. S. No. 24–339 A.)

QUANTITY: 75,000 tablets and capsules, at Chicago, Ill., in possession of Grady's Rx Pharmacy.

SHIPPED: Prior to 10–14–64, from outside the State of Illinois.

LIBELED: 10–14–64, N. Dist. Ill.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since the article was not to be dispensed upon prescription.

DISPOSITION: 12–2–64. Default—delivered to the Food and Drug Administration.

8459. Amphetamine-containing tablets and/or capsules, penicillin tablets, and barbiturate-containing tablets and/or capsules. (F.D.C. No. 50843. S. Nos. 10–163/5 A, 10–721/2 A, 10–733 A.)

QUANTITY: Unknown quantities of tablets and capsules, at Galax, Va., in possession of Carl Royal.

SHIPPED: Prior to 11–20–64, from outside the State of Virginia, by unknown shipper.

LIBELED: 11–20–64, W. Dist. Va.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement, since the articles were prescription drugs, and they were in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs.

DISPOSITION: 2–5–65. Default—destruction.

8460. Glu-Salgin capsules. (F.D.C. No. 50558. S. No. 35–128 A.)

QUANTITY: 8 cases, each containing 12 100-capsule btls., and 39 500-capsule btls., at Chattanooga, Tenn.

SHIPPED: On an unknown date during 1964, from Columbus, Ohio, by Warren-Teed Products Co.

LABEL IN PART: (Btl.) "Warren-Teed Glu-Salgin Each capsule contains: Glucuronolactone 0.150 Gm. (2½ grs.) Dipyrone 0.100 Gm. (1½ grs.) Salrin (Brand of Salicylamide) 0.325 Gm. (5 grs.) Dosage * * * Caution: Federal law prohibits * * * The Warren-Teed Products Co. Columbus, Ohio. Indications: For relief of pain due to rheumatic conditions, arthritis, bursitis, gouty arthritis, sciatica, neuritis, and neuralgia Contraindications."

RESULTS OF INVESTIGATION: Analysis showed that the article contained dipyrone.

LIBELED: 8–25–64, E. Dist. Tenn.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use and it was not entitled to any exemption from that requirement, since it was a prescription drug and its labeling failed to bear adequate information for its use including effects, dosages, frequency and duration of administration and relevant hazards, containdications, side effects and precautions under which practitioners could use the drug safely and for the purposes for which it was intended.

DISPOSITION: 12–9–64. Default—destruction.

8461. Carbamine. (F.D.C. No. 49362. S. No. 227 X.)

QUANTITY: 3 "Deal #1" pkgs., 10 boxes of 50 6-gram packets, 8 boxes of 12 6-gram packets, 24 boxes of 8 6-gram packets, and 26 boxes of 4 6-gram packets, at Columbia, S.C.

SHIPPED: On 7–2–63 and 7–8–63, from Miami, Fla., by Consumer Products Div., Key Pharmaceuticals, Inc.

LABEL IN PART: "Carbamine * * * Soothes and promotes healing of irritated membranes Quick Relief of Acid Indigestion, Upset Stomach, Gastritis, Heartburn Due to Gastric Hyperacidity, Discomfort From TOO MUCH FOOD OR DRINK * * * Directions * * * Active Ingredients: Carbamine, N.F. Sodium Bicarbonate, U.S.P. Citric Acid, U.S.P. * * * Consumer Products Division Key Pharmaceuticals, Inc. Miami 37, Florida."

RESULTS OF INVESTIGATION: Advertisements for the article, reading in part "Medical Science Announces New Relief for Acid Indigestion–Heartburn-Sour Stomach Prescribed by Doctors For Treatment of Peptic Ulcers Carbamine Now Available Without Prescription * * * Consumer Products Division, Key Pharmaceuticals, Inc., Miami, Fla." were run in the local newspapers and spot announcements were run by a local radio station during the period of 7–2–63 through 8–20–63, offering the article for peptic ulcers and for promoting healing of stomach membranes. All material used for the advertisements and announcements was supplied on behalf of Key Pharmaceuticals, Inc.

LIBELED: 10–18–63, E. Dist. S.C.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements which represented and suggested that the article was adequate and effective in the treatment and prevention of gastritis and upset stomach and for healing irritated stomach membranes, which statements were false and misleading, since the article was not adequate and effective for such purposes when the article was used as directed in its labeling; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in the conditions for which it was intended and recommended in the newspaper and radio advertising, namely, peptic ulcers, gastritis, upset stomach, and for healing irritated stomach membranes, since adequate directions for use could not be written for the ordinary lay person.

DISPOSITION: Key Pharmaceuticals, Inc., Miami, Fla., filed a claim and an answer denying that the article was misbranded. On 2–28–64, the court granted the claimant's motion for removal of the cause to the United States District Court for the Middle District of Florida. On or about 6–16–64, the Government served written interrogatories upon the claimant, which were not answered. On 11–5–64, a default decree of condemnation was entered and the article was ordered destroyed.

8462. Multiglands injection. (F.D.C. No. 50701. S. Nos. 53–646/7 A, 53–650 A, 53–652 A.)

QUANTITY: 191 30-cc. vials at Detroit and Dearborn, Mich.

SHIPPED: Between 6–23–64 and 8–4–64, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Some labels—vial and ctn.) "Multigland (Plurigland Extract) Intramuscular Only Caution * * * Richlyn Laboratories, Philadelphia, Pa. Each 2 cc. contains * * * Dose * * * Sterile" and "Multiple Dose Vial Multiglands with D-Amphetamine Caution * * * Richlyn Laboratories Philadelphia, Pa. Each 2 cc. contains * * * Dose: 1–2 cc. intramuscularly Sterile * * * Lot No. 1417."

ACCOMPANYING LABELING: Package inserts entitled "Multiglands Extract and Multiglands Extract with D-Amphetamine Composition * * * Action & Uses * * * in the management of dysmenorrhea, amenorrhea, and disturbances of the endocrine system. Administration & Dosage * * * Contraindications * * * October, 1963" and "Multiglands Extract and Multiglands Extract with D-Amphetamine Composition * * * Actions & Uses: Non specific protein therapy. Dosage & Administration * * * Contraindications * * * Caution * * * December, 1962."

RESULTS OF INVESTIGATION: Analysis of previous lots of different codes of the article had shown that it contained approximately 0.029 milligrams to 0.040 milligams of iodine (in combined form) per cubic centimeter.

LIBELED: 11–13–64, E. Dist. Mich.

CHARGE: 502(a)—(all lots except No. 1417) when shipped, the accompanying labeling, namely, the above-described package inserts, contained false and misleading representations and suggestions that the article was adequate and effective in the treatment of amenorrhea and disturbances of the endocrine system; and 502(f)(1)—(all lots) the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to bear, as required by regulations, adequate information for its use including effects and any relevant hazards, contraindications, side effects and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 1–7–65. Default—destruction.

8463. Reviv-A-Tone units. (F.D.C. No. 47324. S. No. 48–013 P.)

INFORMATION FILED: 4–21–64, E. Dist. Mich., against Victor A. Kalish, and John M. McFarland, partners in the Reviv-A-Tone Therapy Co., Detroit, Mich.

SHIPPED: 5–23–59, from Detroit, Mich., to Boston, Mass.

LABEL IN PART: (Dial labels) "Reviv-A-Tone Health Unit Reviv-A-Tone Therapy Co. Detroit 3, Mich."

ACCOMPANYING LABELING: Leaflet entitled in part "Reviv-A-Tone and Deep Heat."

RESULTS OF INVESTIGATION: Investigation indicated that the *Reviv-A-Tone device* was a combination vibrating and heat-producing device designed for plugging into the usual household electrical current and that, in shape, it somewhat resembled a pillow with arms, and had dial controls for both the heating and the massaging phases.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the devices were an adequate and effective treatment for nervous tension, poor circulation, periodic cramps, lower backaches, and arthritis, and were effective in reducing weight and in spot-reducing specific areas of the body; and 502(f)(1)—the labeling of the devices failed to bear adequate directions for use in the treatment of the diseases, symptoms and conditions for which they were intended, namely, headache, sinus conditions, migraine headaches, rheumatism, aches, pains, backache and deep heat therapy.

PLEA: Nolo contendere.

DISPOSITION: On 8–13–64, Kalish was placed on probation for 2 years; and on 2–18–65, McFarland was fined $250 and placed on probation for 2 years.

8464. Niagara devices. (F.D.C. No. 50682. S. No. 42–582 A.)

QUANTITY: 15 *chairs*, 2 *heat massage pad devices*, 3 *Thermo-Cyclopad devices*, 1 *Carssage unit device*, 5 *Dual Thermo-Cyclopad devices*, 3 *hand unit devices*, 2 *Roll 'N'-Pin devices*, and 1 *chaise lounge device*, at Salt Lake City, Utah, in possession of Niagara of Utah.

SHIPPED: On unknown dates during 1963 and 1964, through 9–23–64, from Los Angeles, Calif., or Adamsville, Pa., by Niagara Therapy Manufacturing Corp.

LABEL IN PART: (Tag on chair) "Made by Niagara Therapy Mfg. Corp., Brocton, New York"; (devices) "Heat Massage Pad * * * by Niagara * * * Cyclo Massage Cycloid Action Niagara Therapy Mfg. Corp. Brocton, N.Y.,"

"Niagara Thermo-Cyclo Pad Cyclo-Massage Cycloid Action Niagara Therapy Mfg. Corp. Brocton, N.Y.," "Carssage Unit * * * Cyclo-Massage and Cycloid Action * * * Niagara Therapy Mfg. Corp. Brocton, N.Y.," "Niagara Dual Thermo-Cyclopad Massage Unit * * * With cycloid action * * * Niagara Therapy Manufacturing Corp. Adamsville, Pa. Brocton, N.Y.," "Niagara Hand Unit Niagara Therapy Mfg. Corp. Brocton, N.Y.," and "Roll 'N'-Pin * * * Revo-Life Inc. Adamsville, Penna."

ACCOMPANYING LABELING: Leaflets entitled "Here's Massage for Week-End Athletes," "Modern Medicine Newsfront," and "Cyclo-Massage Speeds Healing of Bruises, Sprains"; pamphlets entitled "American Journal of Physical Medicine"; brochures entitled "Research Report Common Tension Fatigue"; booklet entitled "More Zestful Living Through Research"; an "Instruction Manual," and books entitled "Dealer's Guide."

RESULTS OF INVESTIGATION: The articles consisted of electrical devices containing vibratory mechanisms and/or units for the production of heat, which devices were intended for home application to the body or, in the case of the *Carssage device*, for use by the driver or passenger in an automobile.

LIBELED: 10–22–64, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective for the treatment of arthritis, rheumatism, bursitis, muscular spasm, tension, sleeplessness, fatigue, aches and pains, lumbago, fibrositis, to stimulate circulation, and to maintain good health; and 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use in the treatment of high blood pressure, strokes, heart attacks, for weight control, slowing down the aging process, bringing life to stillborn babies, removing dead tissues, aiding the hard of hearing, removing impurities from the body and breaking down calcium deposits between the joints, which were the conditions and purposes for which the articles were recommended in oral statements made on 9–22–64, by Mrs. Jenny Vance, saleswoman for Niagara of Utah, at the Niagara exhibit, Industrial Arts Building, Utah State Fair, Salt Lake City, Utah.

DISPOSITION: On 10–28–64, seizure was made of the accompanying labeling of the devices but no seizure was made of the devices because none remained on hand at that time. On 1–23–65, no claimant having appeared, the court entered a decree of condemnation and destruction as to the labeling seized.

8465. Sauna Bath units. (F.D.C. No. 50407. S. No. 96–877 A.)

QUANTITY: 3 devices at Palo Alto, Calif.

SHIPPED: Between 3–10–64 and 5–6–64, from Bellevue, Wash., by Metos Sauna, Inc.

LABEL IN PART: "Metaliteos of Helsinki Mali Star * * * Metos Suomi Finland."

ACCOMPANYING LABELING: Books entitled "Sauna The Way To Health" by S. C. Olin, and leaflets entitled "Metos Sauna The Finnish Way to Health and Beauty."

RESULTS OF INVESTIGATION: The article consisted of unvented heating units that were thermostatically controlled. Heat was transferred from the electrical element to special rocks on the top of the units for the purpose of absorbing and holding the heat.

LIBELED: 7-28-64, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for clearing up acne; improving circulation; reducing weight; aiding fertility (pregnancy); physical fitness; longevity; increasing the supply of milk in nursing mothers; chronic rheumatic ailments; chronic arthritis; backache; blackheads (the forerunner of acne and boils); boils; wrinkles; sinus troubles; inflammations; swellings; slow-healing wounds; common cold; gaining weight; as a killer of disease and restorer of health, energy, strength and endurance; activating the invalid; purging the firm and aged; as a beauty treatment; purifying the skin; building a robust, vigorous body, reflecting manly health, and producing womanly beauty; and 502(f)—the labeling of the article failed to bear (1) adequate directions for use for all the above-named conditions and purposes; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe duration of administration or application in such manner and form as are necessary for the protection of the user.

DISPOSITION: 11-19-64. Consent—claimed by the Finnish American Sauna Co., Palo Alto, Calif., for relabeling.

8466. Champion Juicer device. (F.D.C. No. 50681. S. No. 42-580 A.)

QUANTITY: 2 devices, at Salt Lake City, Utah, in possession of M.C. Weber & Co.

SHIPPED: On unknown date, from Lodi, Calif., by W.R. Laboratories.

LABEL IN PART: (Metal plate on device) "Champion Juicer * * * Manufactured by Plastaket Mfg. Co. Lodi, Calif."

ACCOMPANYING LABELING: Leaflets entitled "What the Champion Juicer Will Do . . .," "Test Made by Neutral Testers with the Champion and a New Centrifugal Juicer," and "The Simple Understanding of Checking the Efficiency of a Juicer –By– W.R. Laboratories"; a business reply card entitled "M. C. Weber & Company"; a leaflet entitled "Food Facts The Wonders of Carrot Juice, by John B. Lust," and a green paper-backed book entitled "Raw Vegetable Juices – What's Missing in Your Body, by N. W. Walker, Doctor of Science."

RESULTS OF INVESTIGATION: The article was an electrical device designed for home use for the purpose of extracting juices from vegetables and fruits.

The leaflets "Food Facts" and the business reply cards were printed locally on order of M.C. Weber & Co., and the other leaflets described above were received by the dealer with the devices.

The book "Raw Vegetable Juices" was used, displayed, discussed, and quoted from, by the dealer, in talks with prospective purchasers of the devices.

LIBELED: 10-29-64, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article, by reason of its use in extracting raw fruit and vegetable juices, was adequate and effective as a health aid in the treatment of infections of the bladder, kidneys, alimentary tract, mouth, tongue, tonsils, sinuses, ear canal, eyes and tear ducts; and to build up and maintain the health of both mother and the developing child; to prevent and treat cancer and other diseases and medical conditions, including Addison's disease, anemia, angina pectoris, tuberculosis,

and the other diseases and medical conditions which were alphabetically listed (from acidosis to, and including, varicose veins) in the aforesaid green paper-backed book; that in relation to the use of the device, it was not the food in your life which counts but the fact that the device prepared a juice which retained life in your food and which was of special dietary value; and that use of the product produced by the device would result in the rebuilding and regeneration of body cells and tissues, and result in good health and energy for the entire family; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the prevention and treatment of heart attacks, reduction of body weight, hastening of the digestion, and prevention of harm from pulp, which were the conditions and purposes for which the article was recommended in oral statements made at the M. C. Weber exhibit at the Industrial Arts Building No. 1, Utah State Fair, on 9–22–64, by salesmen for M. C. Weber & Co.

DISPOSITION: 1–15–65. Consent—claimed by M. C. Weber & Co., Charles Halford, and Wilford Weight, and released to them. The accompanying labeling which had been seized was destroyed.

DRUGS FOR VETERINARY USE

8467. Food supplement for animals. (F.D.C. No. 50668. S. No. 70-558 A.)

QUANTITY: 275 50-lb. bags, at Doland, S. Dak., in possession of Doland Mobile Milling Co.

SHIPPED: 9–9–64, from Des Moines, Iowa.

ACCOMPANYING LABELING: Brochures entitled "64 Vimin Poultry and Livestock Food Supplements" and "The Breakthrough."

RESULTS OF INVESTIGATION: The dealer had on hand the above brochures which were used in promoting sales of the article.

LIBELED: 10–23–64, Dist. S. Dak.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective to decrease animal susceptibility to disease; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use to grow hair on bald heads, relieve the pain and crippling of arthritis, and the aches and pains of rheumatism in humans, which were the conditions and purposes for which the article was offered by John Felderman, an employee of the dealer.

DISPOSITION: 11–23–64. Consent—claimed by Doland Mobile Milling Co., and John Felderman, and released for use as fertilizer. The labels and labeling were destroyed.

8468. Feed supplement. (F.D.C. No. 50431. S. No. 42-464 A.)

QUANTITY: 3 bags, at Salt Lake City, Utah, in possession of Miller's Honey Co., Inc.

SHIPPED: 3–16–64, from San Francisco, Calif.

LABEL IN PART: (Bag) "Feed Supplement Source of Oxytetracycline * * * Net Wt. 50 Lbs. Caution: For Manufacturing."

RESULTS OF INVESTIGATION: The article was intended for repacking into 1-lb. bags by the dealer, Miller's Honey Co., Inc., for use in treating disease conditions of bees which produce honey for food purposes.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended.

DISPOSITION: 10–20–64. Default—destruction.

DRUGS WITHOUT ASSURANCE OF CURRENT GOOD MANUFACTURING PRACTICE*

8469. **Various prescription and nonprescription drugs.** (Inj. No. 495.)

COMPLAINT FOR INJUNCTION FILED: 9–17–64, E. Dist. Mich., against Camall Co., a corporation, Detroit, Mich., and Eugene M. Schmall, president.

METHOD OF OPERATION: The defendants were engaged in the business of packing, labeling, holding, and distributing articles which were drugs within the meaning of the Act. A number of the drugs which the defendants packed, labeled, held and distributed had been shipped in interstate commerce into the State of Michigan. A number of the drugs which the defendants packed, labeled, held, and distributed were articles which had been manufactured or processed within the State of Michigan from components which were shipped in interstate commerce into the State of Michigan. The defendants also distributed a number of drugs which they had packed, labeled, and held, in interstate commerce.

CHARGE: The complaint charged that the methods used in or the facilities or controls used for the manufacture, processing, packing or holding of drugs did not conform to or were not operated or administered in conformity with good manufacturing practice to assure that they met the requirements of the Act as to safety, and had the identity and strength, and met the quality and purity characteristics, which they purported or were represented to possess, which caused the drugs to be adulterated when shipped and while held for sale within the meaning of 501(a)(2)(B). The complaint alleged further that the defendants refused to permit an inspection, as authorized by 704, by Food and Drug inspectors, of the place owned and operated by the defendants at which they packed, labeled, held, or distributed articles of drug, including the records, files, papers, processes, controls, or facilities relating to prescription drugs.

DISPOSITION: 10–1–64. The defendants, having consented to the entry of a decree and before any testimony had been taken, the court entered a decree of permanent injunction which provided that Camall Co., and Eugene M. Schmall, be perpetually restrained and enjoined from directly or indirectly doing any of the following acts:

(1) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, any article of drug which is adulterated within the meaning of 501(a)(2)(B), in that the methods used in or the facilities or controls used for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with good manufacturing practice to assure that such drug meets the requirements of the Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

(2) Doing any act which results in any article of drug, which is being held for sale after its shipment, or the shipment of any of its components, in inter-

*See also Nos. 8441, 8442.

state commerce, becoming adulterated within the meaning of 501(a)(2)(B) as described above;

(3) Engaging in the packing, labeling, and distributing of articles of drug unless and until the defendants permit an inspection of any place which they own or operate where they pack, label, hold, or distribute drugs as authorized by 704;

(4) Refusing to permit inspection as authorized by 704, by Food and Drug inspectors, of any place which is owned or operated by the defendants at which they pack, label, hold, or distribute any article of drug or refusing to permit inspection of any of the records, files, papers, processes, controls, or facilities relating to prescription drugs as authorized by 704;

(5) Engaging in the activities of packing, labeling, and distributing of articles of drug which are held for sale after shipment in interstate commerce, or after the shipment of any of its components in interstate commerce, or which are to be introduced and delivered for introduction into interstate commerce, unless and until adequate methods and controls are established and administered at any and every place where such activities are conducted which are in conformity with good manufacturing practice as prescribed by regulations, which methods and controls shall specifically include, among other things, the following: (a) the building is maintained in a clean and orderly manner; (b) the equipment is kept clean and is constructed so that any surfaces which come into contact with drugs do not significantly affect their identity, strength, quality, and purity; (c) the key personnel involved in the control of drugs have a background of appropriate experience and education or combination thereof for assuming responsibility to assume that the drug has the safety, identity, strength, quality, and purity that it purports to possess; (d) all containers, closures and component parts of packages are suitable for their intended use; (e) packaging and labeling controls are instituted to assure that only drugs which meet the requirements of safety, identity, strength, quality and purity are distributed; to prevent mix-ups; to assure that only the correct labeling is used; to identify all drugs with lot or control numbers which show the history of the products; (f) labeling is stored so that no mix-ups shall occur, and a running inventory is kept on all such labeling; (g) no packaging and labeling is conducted on a batch of drug until excess containers, and labels from the prior operation are removed to prevent mix-ups; (h) complete records of distribution are kept as provided by regulations; and Food and Drug inspectors are granted access for the purpose of inspecting the premises, which inspection will also extend to the appropriate records, and a report is made by the inspectors, to this court, that the established methods and controls are in conformity with current good manufacturing practice.

8470. Dextro-amphetamine sulfate and amobarbital capsules. (F.D.C. No. 51288. S. No. 17-087 B.)

QUANTITY: 121 1,000-capsule btls. at Los Angeles, Calif.

SHIPPED: 1-26-65, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: "Dextro Amphetamine Sulfate & Amobarbital No. 3 Capsules * * * Each Capsule Contains: Dextro Amphetamine Sulfate 15 mgm. Amobarbital 90 mgm. * * * Caution: Zenith Laboratories, Inc. * * * Englewood, New Jersey."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 80.6 percent of the declared amount of amobarbital.

LIBELED: 4–27–65, S. Dist. Calif.

CHARGE: 501(a)(2)(B)—when shipped, the methods used in the manufacture of the article were not in conformity with current good manufacturing practice to assure that it had the identity and strength which it purported to possess; 501(c)—the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Each Capsule Contains: * * * Amobarbital 90 mgm." was false and misleading.

DISPOSITION: 5–18–65. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

8471. Trisureid tablets. (F.D.C. No. 50393. S. No. 3–122 A.)

QUANTITY: 1,371 100-tablet btls. at Atlanta, Ga.

SHIPPED: 1–31–64, from Hialeah, Fla., by Pharmaceutical Enterprises, Inc.

LABEL IN PART: "Reid Trisureid * * * Each Tablet Contains: Sulfadiazine 2½ grs. Sulfamerazine 2½ grs. Sulfamethazine 2½ grs. Total Micro-Sulfas 7½ grs. Caution: Federal law * * * Distributed by Reid Laboratories, Inc. Atlanta, Georgia Warning * * * Average Dose."

ACCOMPANYING LABELING: Package insert reading in part "Trisureid Trisulfapyrimidines, U.S.P. Antibacterial."

LIBELED: 7–17–64, N. Dist. Ga.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, "Trisulfapyrimidines Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the standard set forth in such compendium; and 502(a)—the statement in the package insert "Trisulfapyrimidines, U.S.P." was false and misleading as applied to a product which failed to meet the United States Pharmacopeia standard for disintegration of "Trisulfapyrimidines Tablets."

DISPOSITION: 8–24–64. Consent—claimed by Reid-Provident Laboratories, Inc., for reprocessing.

8472. Marla contact lens wetting solution. (F.D.C. No. 50751. S. No. 94–086 A.)

QUANTITY: 252 4-oz. btls. at St. Louis, Mo.

SHIPPED: 9–24–64, from Buffalo, N.Y., by Santa Pharmaceuticals, Inc.

LABEL IN PART: "Marla Antiseptic Wetting and Soaking Solution For Contact Lenses * * * Bacteriacidal * * * Contains: Phenoxynate Manufactured in U.S.A. By Santa Pharmaceuticals, Inc., Buffalo 16, N.Y."

LIBELED: 11–27–64, E. Dist. Mo.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess; and 502(a)—the label statements "Antiseptic" and "Bacteriacidal" were false and misleading as applied to a product which was contaminated with viable micro-organisms.

DISPOSITION: 2–15–65. Default—destruction.

8473. Adhesive bandages. (F.D.C. No. 50420. S. Nos. 25–933/5 A.)

QUANTITY: 28 100-unit ctns., 120 12-unit ctns., and 40 12-unit ctns., at Chicago, Ill.

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*See also Nos. 8441–8443, 8449, 8455, 8470.

SHIPPED: 5–15–64, from New Rochelle, N.Y., by Hampton Manufacturing Co.

LABEL IN PART: (Ctn.) "Blue Cross Plastic Adhesive Bandages Sterile Waterproof Directions * * * Caution * * * Hampton Manufacturing Co. New Rochelle, N.Y." and "Blue Cross Adhesive Bandages Hampton Manufacturing Co. New Rochelle, N.Y."; (bandage) "Blue Cross Sterilized Adhesive Bandage."

LIBELED: 8–4–64, N. Dist. Ill.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as "Adhesive Absorbent Bandage (Adhesive Absorbent Compress)," and its quality and purity fell below the standard set forth in the United States Pharmacopeia for such article since the article was not sterile but was contaminated with living micro-organisms; and 502(a)—the label statements "Sterile" (28-carton lot) and "Sterilized" (120-carton lot bandage label) were false and misleading as applied to an article that was not sterile but was contaminated with living micro-organisms.

DISPOSITION: 9–9–64. Default—destruction.

8474. Clinical thermometers. (F.D.C. No. 49893. S. Nos. 79–451/2 A.)

QUANTITY: 549 thermometers at Clifton, N.J.

SHIPPED: Between 11–14–62 and 5–1–63, from Ridgewood, N.Y., by Cornell Instrument Co.

LABEL IN PART: (Box) "Tested Regent Stubby [or "Rectal"] fever thermometer * * * Cornell Instrument Co., Inc. Ridgewood 37, N.Y."

ACCOMPANYING LABELING: Certificates reading in part "carefully inspected, tested and checked with instruments tested by the National Bureau of Standards."

RESULTS OF INVESTIGATION: Examination of 23 thermometers showed that 18 failed to meet the requirements for accuracy when tested as described in the specifications issued by the National Bureau of Standards.

LIBELED: 5–13–64, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they purported and were represented to possess; and 502(a)—the statement in the labeling "carefully inspected, tested and checked with instruments tested by the National Bureau of Standards" was false and misleading.

DISPOSITION: 7–7–64. Default—destruction.

8475. Clinical thermometers. (F.D.C. No. 49961. S. No. 50–124 A.)

QUANTITY: 99 devices in pkgs. of 12 each, at Detroit, Mich.

SHIPPED: 1–30–64, from Passaic, N.J., by Omega Hospital Supply, Inc.

LABEL IN PART: (Pkg.) "Permark Thermometer * * * medical mercury thermometers * * * Protects your patients * * * your nurses * * * your physician * * * Directions For Using Fever Thermometers * * * Manufactured by Ex-Ell Thermometer Corporation Exclusively for Omega Hospital Supply, Inc., * * * Passaic, N.J."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 3 failed to comply with the requirements for accuracy when tested as described in specifications issued by the National Bureau of Standards.

LIBELED: 4–8–64, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the label statements "medical mercury thermometers," "Directions For Using Fever Thermometers," and "Protects," were false and misleading as applied to an article failing to comply with requirements for accuracy for clinical thermometers.

DISPOSITION: 8–12–64. Default—destruction.

8476. Rubber prophylactics. (F.D.C. No. 49880. S. No. 2–144 A.)

QUANTITY: 48 ½-gross ctns., each ctn. containing 24 3-unit pkgs., at Tampa, Fla.

SHIPPED: 1–3–64, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Ctn.) "Saxon Lubra Pack Micro-Thin Transparent Prophylactics * * * Sold for the Prevention of Disease Only * * * Manufactured by Circle Rubber Corp. Newark, N.J." and (pkg.) "Lubra Pak Saxon Micro-Thin Transparent Prophylactics * * * Sold for the Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination of 202 prophylactics showed that 0.99 percent contained holes.

LIBELED: On or about 3–2–64, M. Dist, Fla.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement (package and carton) "Sold for the Prevention of Disease Only" was false and misleading.

DISPOSITION: 4–25–64. Default—destruction.

8477. Rubber prophylactics. (F.D.C. No. 49946. S. No. 8–278 A.)

QUANTITY: 120 ctns., each containing 48 3-unit pkgs., at Norfolk, Va.

SHIPPED: 2–4–64, from Akron, Ohio, by Allied Latex Sales Co.

LABEL IN PART: (Pkg.) "Gems Prophylactics * * * Sold For The Prevention of Disease Only * * * Mfd. For Allied Latex Sales Co. Inc., N.Y. 5, N.Y."

RESULTS OF INVESTIGATION: Examination showed that approximately 1.3 percent were defective in that they contained holes.

LIBELED: On or about 3–24–64, E. Dist. Va.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements (package and unit) "Sold For ["The"] Prevention of Disease Only" were false and misleading as applied to a product containing holes.

DISPOSITION: 4–28–64. Default—destruction.

8478. Rubber prophylactics. (F.D.C. No. 49934. S. No. 38–644 A.)

QUANTITY: 91 ctns., each containing 48 plastic 3-unit tubes, at Dallas, Tex.

SHIPPED: Between 1–3–64 and 1–27–64, from Akron, Ohio, by Allied Latex Sales Co.

LABEL IN PART: (Tube) "Sold For The Prevention of Disease Only Clear-Tone * * * Transparent Prophylactics Manufactured for Allied Latex Sales Co. New York, N.Y."

RESULTS OF INVESTIGATION: Examination showed that approximately 0.85 percent of the article was defective in that it contained holes.

LIBELED: 4–20–64, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement (tube and unit) "Sold For ["The"] Prevention of Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 8–24–64. Default—destruction.

8479. Rubber prophylactics. (F.D.C. No. 49851. S. No. 55–464 A.)

QUANTITY: 8 cases of 25-gross ctns., each ctn. containing 72 2-unit pkgs., at North Kansas City, Mo.

SHIPPED: 1–23–64, from Durham, N.C., by Barnetts, Inc.

LABEL IN PART: (Pkg.)"Kent 2 Prophylactics Sold For The Prevention of Disease Only—Manufactured For Allied Latex Sales Co. Newark, N.J." and (unit) "Barnett Packaging Inc. Durham, N.C. Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that approximately 0.83 percent of the article was defective.

LIBELED: 5–24–64, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements (package and unit) "Sold For ["The"] Prevention of Disease Only" were false and misleading as applied to a product containing holes.

DISPOSITION: 7–21–64. Default—destruction.

8480. Rubber prophylactics. (F.D.C. No. 50243. S. No. 4-224 A.)

QUANTITY: 97 ctns., each ctn. containing 72 2-unit pkgs., at Macon, Ga.

SHIPPED: 4–17–64, from Durham, N.C., by Barnetts, Inc.

LABEL IN PART: (Pkg.) "Safe-Tex Prophylactics * * * Sold And Intended To Be Used As A Preventive Of Disease Only * * * Product Of Barnett Dist. Co. Durham, N.C."

RESULTS OF INVESTIGATION: Examination of 180 prophylactics showed that 2.2 percent were defective, in that they contained holes.

LIBELED: 6–26–64, M. Dist. Ga.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold And Intended To Be Used As A Preventive Of Disease Only" was false and misleading.

DISPOSITION: 9–1–64. Default—destruction.

8481. Rubber prophylactics. (F.D.C. No. 50120. S. Nos. 54–890/1 A.)

QUANTITY: 20 ctns., each ctn. containing 72 2-unit pkgs., and 16 ctns., each ctn. containing 72 3-unit pkgs., at Atlanta, Ga.

SHIPPED: 4–17–64, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics [or "Viking Prophylactics"] * * * Sold For The Prevention of Disease Only * * * M & M Rubber Co., Kansas City 8, Mo."

RESULT OF INVESTIGATION: Examination showed that 0.9 percent of the units tested were defective in that they contained holes.

LIBELED: On or about 5–23–64, N. Dist. Ga.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they were purported to possess; and 502(a)—the label statements "Sold For The Prevention of Disease Only" were false and misleading.

DISPOSITION: 7–13–64. Default—destruction.

8482. Rubber prophylactics. (F.D.C. No. 49854. S. No. 18–233 A.)

QUANTITY: 15 gross, in pkgs. of 12 each, at Johnstown, Pa.

SHIPPED: 1–16–64, from Cleveland, Ohio, by Schaeffer Products Co.

LABEL IN PART: (Pkg.) "Rolled Frat House Prophylactics Packed by Schaeffer Products Co., Cleveland, Ohio * * * Sold only to Prevent Disease."

RESULTS OF INVESTIGATION: Examination of 50 units showed that 4 percent were defective in that they contained holes.

LIBELED: 3–26–64, W. Dist. Pa.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold only to Prevent Disease" was false and misleading.

DISPOSITION: 4–23–64. Default—destruction.

8483. Rubber prophylactics. (F.D.C. No. 50447. S. No. 49–063 A.)

QUANTITY: 9 ctns., each containing 12 12-unit pkgs., and 19 ctns., each containing 48 3-unit pkgs., at Grand Rapids, Mich.

SHIPPED: Between 1–1–63 and 12–31–64, from Cleveland, Ohio, by Schaeffer Products Co.

LABEL IN PART: (Ctn.) "Frat House 12's Rolled Prophylactics * * * Sold For Prevention of Disease Only Schaeffer Products Co., Inc. Cleveland, Ohio."

RESULTS OF INVESTIGATION: Examination showed that approximately 0.9 percent of the article was defective in that it contained holes.

LIBELED: On or about 8–11–64, W. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements (carton of 12 packages) "Sold For Prevention of Disease Only" and (package) "Sold only to prevent disease" were false and misleading as applied to a product containing holes.

DISPOSITION: 9–8–64. Default—destruction.

8484. Rubber prophylactics. (F.D.C. No. 50234. S. No. 19–936 A.)

QUANTITY: 5 cases, each containing 40 12-pkg. ctns., each pkg. containing 4 3-unit boxes, at Pittsburgh, Pa.

SHIPPED: 5–21–64, from Akron, Ohio, by Killashun Sales Div. of Akwell Corp.

LABEL IN PART: (Pkg. and box) "Silvertex Match Folder Type Prophylactics * * * Sold Only For The Prevention of Disease * * * Mfd. by the Killian Mfg. Div. of the Akwell Corp. Akron, Ohio," and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 1.4 percent of the units tested were defective.

LIBELED: 6–19–64, W. Dist. Pa.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements "Sold Only For The Prevention of Disease" and "Sold For Prevention of Disease Only" were false and misleading.

DISPOSITION: 7–13–64. Default—destruction.

8485. **Rubber prophylactics.** (F.D.C. No. 50275. S. No. 2–749 A.)

QUANTITY: 4,400 ctns., each containing 144 units, at Columbia, S.C.

SHIPPED: On 8–9–63 and 9–12–63, from Akron, Ohio, by Killashun Sales Div. of Akwell Corp.

LABEL IN PART: (Ctn.) "Rolled Koin-Pack * * * Manufactured by L. E. Shunk Latex Products Div. of The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination of 150 units showed that 2 were defective in that they contained holes.

LIBELED: 6–10–64, E. Dist. S.C.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess.

DISPOSITION: 7–20–64. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

8486. **Trimeze capsules.** (F.D.C. No. 50677. S. Nos. 104–033/4 A.)

QUANTITY: 20 30-capsule boxes, 11 60-capsule boxes, 25 ctns., each containing 6 60-capsule boxes, and 7 ctns., each containing 12 30-capsule boxes, at Seattle, Wash.

SHIPPED: Between 7–13–64 and 8–12–64, from Woodland Hills, Calif., by Executive Products.

LABEL IN PART: (Box) "Timed Disintegrating Trimeze Trimeze a reducing aid Directions—One capsule, Once Daily * * * Each capsule contains as active ingredients: Phenylpropanolamine Hydrochloride 75 mg. * * * Caution * * * Executive Products Los Angeles, California Makes a low calorie diet easy!"

ACCOMPANYING LABELING: (Insert) "Eat What you like but. . . ."

LIBELED: On or about 10–19–64, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the name "*Trimeze*" and statements in the labeling contained false and misleading representations that the article was adequate and effective as an aid for reducing; that you might eat what you like but lose weight the comfortable way; that these capsules would supply extra pep and energy and assist in relieving the low-down depressed feeling you usually have on a diet; that you would feel better all day the easy way.

DISPOSITION: 1–7–65. Default—destruction.

8487. **Regimen tablets (6 seizure actions).** (F.D.C. Nos. 49723, 49733, 49748, 49895, 49896, 49977. S. Nos. 33–101 A, 35–001 A; 54–562/3 A; 6–504 A; 50–060 A, 51–222/3 A; 19–374/6 A; 84–839/40 A.)

*See also Nos. 8443, 8449, 8452, 8453, 8455, 8461–8467, 8470–8484.

QUANTITY: 52 78-tablet boxes and 10 156-tablet boxes at Lexington, Ky.; 36 156-tablet boxes and 87 78-tablet boxes at St. Joseph, Mo.; 324 78-tablet boxes and 303 156-tablet boxes at Washington, D.C.; 774 78-tablet boxes and 537 156-tablet boxes at Detroit, Mich.; 318 78-tablet boxes and 76 156-tablet boxes at Pittsburgh, Pa.; and 47 36-tablet boxes and 75 18-tablet boxes at St. Louis, Mo.

SHIPPED: Between 1–1–62 and 1–23–64, from Long Island City, New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen—Tablets * * * contain: (In Green tablets) Vitamin D (irradiated yeast), B_1, B_2, B_6, and C, Niacinamide, Calcium Pantothenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride, Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Ammonium Chloride * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular reading in part "Reduce with the Regimen Plan: A New Dietary Combination to Satisfy Hunger Remove Excess Water Control and Inhibit Appetite Drug Research Corp. New York, New York * * * As Long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss."

LIBELED: 1–15–64, E. Dist. Ky.; 1–24–64, W. Dist. Mo.; 1–30–64, Dist. Columbia; on or about 2–25–64, E. Dist. Mich.; 3–2–64, W. Dist. Pa.; and 4–17–64, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen Plan" could do most everything medical science could do to help one attain one's goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were much more susceptible to cancer.

DISPOSITION: 4–27–64, 3–12–64, 2–28–64, 4–27–64, 4–22–64, 8–14–64. Default—destruction.

8488. **Dr. Hopper's tablets.** (F.D.C. No. 50589. S. No. 32–949 A.)

QUANTITY: 39 ctns., each containing 126 60-tablet btls.; 96 ctns., each containing 12 50-tablet btls.; 1 ctn., containing 52 50-tablet btls.; 35 ctns., each containing 96 100-tablet btls.; 50 ctns., each containing 12 100-tablet btls.; and 1 ctn., containing 64 100-tablet btls., at Princeton, Ky., in possession of Williamson Drug Products, Inc.

SHIPPED: On 2–27–61 and 5–11–61, from Chicago, Ill.

LABEL IN PART: (Btl.) "Dr. Hopper's Tablets For Relief of Gastric Hyperacidity Contents * * * Directions * * * Active Ingredients: Bismuth Subcarbonate, Sodium Bicarbonate, Aluminum Hydroxide, Magnesium Trisilicate, Sodium Citrate, Calcium Carbonate."

ACCOMPANYING LABELING: Letters entitled "Dear Friend" and folders entitled "For Those Who Suffer From Stomach Distress," which were printed locally on order of the dealer.

LIBELED: 9–29–64, W. Dist. Ky.

CHARGE: 502(a)—while held for sale, the labeling of the article contained statements which represented and suggested that the article was adequate and effective for the relief of many causes of stomach distress, upset stomach, nervous stomach, indigestion, gas, and ulcer pain; that excess acid in the stomach was the major cause of stomach distress; that *Dr. Hopper's tablets* coated and protected the irritated surfaces of the stomach lining; that distrubance of the nervous system by poor digestion led to stomach distress; that intake of food and drink, over-hot or cold, might cause stomach pain; that excess acid might be the chief cause of ulcers; that *Dr. Hopper's tablets* would neutralize excess acid in the stomach, relieving irritation and enabling the stomach to function properly and be free of distress symptoms; that the article would give complete and perfect relief from pain; that its use could save the need of surgery; and stop stomach trouble; which statements were false and misleading, since the article was not adequate and effective for such conditions and purposes and since the statements were otherwise contrary to facts.

DISPOSITION: On or about 12–22–64, the claimant, Williamson Drug Products, Inc., Princeton, Ky., filed an answer, denying that the article was misbranded. On 6–7–65, a consent decree of condemnation was entered which provided for the destruction of the promotional material described above and the release of the article to the claimant for relabeling.

8489. Soberettes. (F.D.C. No. 51076. S. No. 61–814 A.)

QUANTITY: 122 boxes, each containing 40 packets, at Phoenix, Ariz.

SHIPPED: 10–25–63, 1–1–64, and unknown date, from San Antonio, Tex., by Universal Pharmaceutical Co.

LABEL IN PART: (Box) "Soberettes For overindulgence in food and drink * * * Universal Pharmaceutical Co. 827 W. Hildebrand San Antonio, Texas."

LIBELED: 2–12–65, Dist. Ariz.

CHARGE: 502(a)—when shipped, the name of the article, "*Soberettes*," and statements in its labeling (box) represented and suggested that the article was adequate and effective to make an intoxicated person sober, which name and statements were false and misleading since the article was not adequate and effective for such purpose.

DISPOSITION: 3–31–65. Default—destruction.

8490. Sun City cold capsules. (F.D.C. No. 50412. S. No. 61–319 A.)

QUANTITY: 70 cases, each containing 48 50-capsule btls., at El Segundo, Calif., in possession of Rabin-Winters Corp.

SHIPPED: 2–5–64 and 3–30–64, from Brooklyn, N.Y.

LABEL IN PART: (Btl.) "Sun City Cold Capsules * * * for relief of nasal congestion due to Colds and Hay Fever Manufactured for Sun City Pharmaceutical Corporation * * * Each Capsule Contains: Belladonna Alkaloids 0.16 mgm. Atropine Sulfate 0.024 mgm. Scopolamine Hydrobromide 0.014 mgm. Hyoscyamine Sulfate 0.122 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. * * * Caution: Not to be used by * * * Dosage: 1 capsule in the morning and 1 capsule at bedtime."

RESULTS OF INVESTIGATION: The article was repacked by the dealer from bulk lots, shipped as described above, into bottles described above and shipped by the dealer to Phoenix, Ariz., and was subsequently returned to the dealer.

LIBELED: 7–28–64, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the repack bottle label contained statements which represented and suggested that a single *Sun City cold capsule* containing the amounts of the ingredients declared in the label would provide continuous relief for approximately 12 hours, from nasal congestion due to the common cold and hay fever; that it would help clear nasal passages; reduce sneezing and itching of the eyes; and reduce running nose and watering of the eyes; which statements were false and misleading, since the article was not adequate and effective for such purposes when taken as directed.

DISPOSITION: 3–26–65. Default—destruction.

8491. Protac capsules. (F.D.C. No. 50391. S. No. 60–264 A.)

QUANTITY: 2,016 10-capsule pkgs. at Garden Grove, Calif.

SHIPPED: 5–18–64, from Buffalo, N.Y., by Republic Drug Co., Inc.

LABEL IN PART: (Pkg.) "Protac Republic Drug Company, Inc. Buffalo * * * 10 Prolonged Action Capsules Just one capsule in the morning and one capsule at bedtime provides continuous relief of nasal congestion due to common colds and hay fever * * * Each capsule contains: Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Scopolamine Hydrobromide 0.014 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Phenylpropanolamine Hydrochloride 50 Mgm. Chlorpheniramine Maleate 1 Mgm. Pheniramine Maleate 12.5 Mgm."

LIBELED: 7–21–64, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling, namely, the package label, contained statements which represented and suggested that a single *Protac capsule* containing the amounts of the ingredients declared in the label would provide 12 hours of continuous relief from excessive nasal discharge, running nose, watering of the eyes, swelling of the nasal tissues, and stuffy congested feeling caused by the common cold and hay fever; which statements were false and misleading since the article was not adequate or effective for such purposes when taken as directed in the labeling.

DISPOSITION: 4–30–65. Default—destruction.

8492. Crown Prince Scalp Formula. (F.D.C. No. 49964. S. No. 49–655 A.)

QUANTITY: 238 4-oz. jars at Fort Wayne, Ind.

SHIPPED: 1–15–64, from Cincinnati, Ohio, by Ivanhoe Corp.

LABEL IN PART: (Jar) "Crown Prince The Scalp Formula For the Head of the House Directions for use * * * Active Ingredients: gum camphor, anhydrous lanolin, cod liver oil and castor oil * * * distributed by Ivanhoe Corporation, Cincinnati, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "Crown Prince The Scalp Formula For The Head of the House" and booklets entitled "Local Treatment of Alopecia Prematura * * * by Frederic Damrau, M.D."

LIBELED: 4–9–64, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for strengthening the hair, adding body to existing hair, and as a significant factor in restoring normal hair growth.

DISPOSITION: The article was claimed by Ivanhoe Corp., on 5–11–64. In October 1964 the Government filed written interrogatories and a pre-trial conference was scheduled on 1–4–65. Claimant failed to appear and failed to answer the interrogatories. The Government thereafter moved for a default judgment which was entered on 2–2–65, providing for the condemnation and destruction of the article.

8493. Face mask kit. (F.D.C. No. 51294. S. No. 15–428 B.)

QUANTITY: 250 ctns., each containing a *face mask kit* consisting of 1 plastic bag, containing a face mask, eye pieces, neck piece, and brochure; 1 plastic btl. containing crystals; 1 plastic btl. containing liquid; 1 clear glass btl. containing liquid; 1 bar of soap; and 1 leaflet, at Anaheim, Calif., in possession of Wonder Products, Inc.

SHIPPED: Between 7–1–63 and 7–31–63, and on unknown date (plastic bag and contents) from Hannover, West Germany and (foaming milk and soap) from St. Paul, Minn.

LABEL IN PART: (Ctn.) "Wonder Products, Inc. 2139–B, W. Ball Rd. Anaheim, Calif."; (plastic bag) "Renee-Derm Gesichtsbade-u. Massagemaske D.B.P. 1053149 u. Ausl. Pat."; (face mask) "Renee-Derm Pat. Made in Germany"; (plastic btl.—crystals) "Formula '18' Contents Net Weight 8 oz. Wonder Products Anaheim, Calif."; (plastic btl.—liquid) "Mr. Mears Foaming Milk Lan-O-Bath Contains Milk and Lanolin Moisturizes Dry Skin * * * Contents 4 Ounces"; (glass btl.) "Wonder Oil Contents 4 Fl. Oz. Wonder Products Company Distributors Anaheim, Calif."; (brochure in bag) "Important For You! Renee-Derm Facial-Balneotherapy"; and (soap bar) "Mr. Mears Complexion Soap with Lanolin."

ACCOMPANYING LABELING: Leaflets entitled "Wonder Mask" and "Renee-Derm Skin Rejuvenator."

RESULTS OF INVESTIGATION: Examination showed the items in the kits to be as follows: foam rubber face mask, eye pieces, and neck piece; the neck piece and face mask having a cloth band attached to each side. The Foaming Milk Lan-O-Bath was a pink, semi-viscid liquid with perfume odor. The Formula 18 was a mixture of white and clear colorless crystals with no odor. The Wonder Oil was a clear, slightly pink, oily liquid with perfume odor. The Complexion Soap was a rectangular-shaped bar having a slight perfume odor.

The leaflets were printed on order of the dealer for the purpose of promoting sales of the kits.

LIBELED: 5–3–65, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling, namely, the leaflets described above, contained statements which represented and suggested that the article was adequate and effective as a treatment for dry, dehydrated, fat, grey, tired, flaccid, or blotchy skin which had lost all its vitality; that use of the article would produce the most wonderful skin that anyone could ever desire; invigorate, nourish, and refresh the skin; correct all skin faults, and signs of degeneration; help repair the effects of deficiencies due to age; massage moisture down into the deepest skin layers; that the article was a revolutionary new method of biological cosmetic treatment which cleansed the skin from within and nourished, tightened, invigorated, and refreshed the skin; improved blood and lymph circulation; accelerated the metabolism, and had a beneficial effect upon the facial nerves; that use of the article made the skin self-sufficient and properly functioning once more; and that it provided

the certain and natural way to hold back the aging of the skin in the most effective manner; which statements were false and misleading, since the article was not adequate and effective for such conditions and purposes, and since the statements were otherwise contrary to fact.

DISPOSITION: 6–16–65. Default—30 each, of the following: *face mask kit*, face mask (part of kit), pamphlets, and letter of instructions in each kit, were delivered to the Food and Drug Administration; remainder destroyed.

8494. Firmatron device. (F.D.C. No. 47555. S. No. 30–135 T.)

QUANTITY: 1 device at Beverly Hills, Calif.

SHIPPED: On 6–13–61, from Dallas, Tex., by Norruth Industries, Inc.

LABEL IN PART: "Firmatron by Norruth * * * Electro-Mechanical Instr. Co. Perkasie, Pa. * * * Serial No. A 1051."

ACCOMPANYING LABELING: Leaflets entitled "Laugh at Birthdays," "What Is Firmatron," and "The New Shape of Things to Come"; and an "Operator's Manual."

RESULTS OF INVESTIGATION: Investigation indicated the article to be a cabinet 24 x 14 x 43 inches, containing a battery-operated impulse generator, a timing device and electrodes applicators. The generator circuit consisted of a transistorized unit operated by a 9-volt battery designed to produce modulated 4,000 and 6,000 c.p.s. pulses. The applicator electrodes were plastic gloves with the conductor built into the fingers or pads with 4 metal button contacts.

LIBELED: 4–19–62, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article, namely, the leaflets and the operator's manual described above, contained false and misleading representations that the article was adequate and effective as a treatment for retarding or repairing the ravages of time as it affects the face and neck; improving the condition of every woman's face and neck regardless of the woman's age; retarding the aging process and reviving facial beauty and youthfulness; overcoming sallow complexion, lines, wrinkles, double chin, crow's feet, sagging flesh, and bags under the eyes; and that, as the "latest miracle of science," the article helped to keep one looking young.

DISPOSITION: On 7–23–62, Firmatron, Inc., New York, N.Y., filed a claim to the article. On the same date, the court approved a stipulation and order which transferred the case to the United States District Court for the Eastern District of New York. On 8–23–62, the claimant filed an answer, denying that the article was misbranded as alleged. On or about 12–3–62, the Government served written interrogatories upon the claimant. The claimant did not answer the interrogatories within 15 days but, on 1–22–63, it requested an extension of time for answer until 2–22–63 which was agreed to by the Government. On 2–20–63, the Government served notice to take depositions. Another extension of time until 3–15–63 was thereafter agreed to for answer to interrogatories and taking of depositions. Subsequently, on 3–27–63, a motion was made by the claimant and argued before the court for an extension of time to answer the interrogatories and take depositions, until 9–30–63. On 3–29–63, the court denied the motion for extension. On 4–8–63, upon the Government's motion for default judgment of condemnation and after argument on such motion, the court entered an order granting the motion and condemning the goods by default. An appeal was taken by the claimant to the United States Court of Appeals for the Second Circuit on the ground that the judge had abused his discretion in granting judgment by default, and on or about

4–19–63, while the case was on appeal the claimant filed an answer to the interrogatories. On 11–20–63, an opinion was handed down by that court reversing the order of the lower court and remanding the action for the opening of the default (324 F 2d 497). On 3–15–65, Firmatron, Inc., having withdrawn its claim and answer, a decree of condemnation was entered ordering the destruction of the article and its accompanying literature.

8495. **Rol-Off device.** (F.D.C. No. 50873. S. No. 27–390 A.)

QUANTITY: 174 devices, at Chicago, Ill., in possession of Patricia Gage (Archer Products).

SHIPPED: The devices were manufactured at Chicago, Ill., from wooden balls, wooden handles, and steel rods which were shipped on or about (wooden balls and handles) 11–7–62, from Montello, Wis., and (steel rods) about November 1962, from Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Instructions For Using the Rol-Off * * * Archer Products * * * Chicago 13, Illinois."

RESULTS OF INVESTIGATION: Examination showed the device to consist of a metal rod with wooden handles about 3½ inches long at each end. Threaded onto the metal rod were 7 wooden balls about 1½ inches in diameter. The device was about 16¼ inches long, and was intended for rolling over the stomach, hips and other parts of the body.

LIBELED: 12–10–64, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the name of the article, "*Rol-Off*," and certain statements in the accompanying labeling of the article, made false and misleading representations and suggestions that use of the article would roll off or reduce body weight; reduce the tummy and hips to give one a firmer, flatter tummy; firm and raise the breasts; and relieve congestion and nervous tension and accompanying headaches.

DISPOSITION: 1–18–65. Default—destruction.

8496. **Figurama Sauna Bath device.** (F.D.C. No. 51306. S. No. 17–257 B.)

QUANTITY: 1 ctnd. device, which consisted of a cabinet and an individually ctnd. heater, at San Diego, Calif., in possession of Home Portable Sauna Bath.

SHIPPED: 3–1–65, from Tijuana, Mexico.

ACCOMPANYING LABELING: Form letter entitled "Home Portable Sauna Bath * * * Dear Customer"; pamphlet entitled "How It Works"; folders entitled "Usted Es Tan Joven Como Se Siente"; and copy of a newspaper tear sheet containing an advertisement from Evening Tribune, San Diego, California, Wednesday, March 17, 1965, reading in part "Home Portable Sauna Bath * * * Relaxes tensions–Stimulates circulation."

RESULTS OF INVESTIGATION: Inspection indicated the article to consist of a portable wood cabinet which contained a portable seat upon which the patient sits during exposure and an electric heater to furnish heat inside the cabinet.

All of the accompanying labeling, except the newspaper tear sheet advertisement, was imported by the dealer from Mexico for use in promoting sales of the article.

LIBELED: 5–21–65, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for muscular pains or stiffness due to any cause,

as an after treatment of injuries and sprains, for weight control, maintaining a proper physical balance, nervous tensions, and that use of the article revitalized the body, eliminated impurities, renewed the body and provided virility, rejuvenation, and renewed energy, as well as penetrating thermal action whenever it was indicated in physical therapy.

DISPOSITION: 7–27–65. Default—destruction.

8497. **Port-A-Sauna steam bath device.** (F.D.C. No. 51385. S. No. 54–675 B.)

QUANTITY: 6 unlabeled devices at Arlington, Va.

SHIPPED: 2–5–65, from Phoenix, Ariz., by Amca, Ltd.

ACCOMPANYING LABELING: Brochures entitled "Port-A-Sauna A Division of Amca Ltd. * * * Alexandria, Va."

RESULTS OF INVESTIGATION: Inspection showed the device to be a fiber glass cabinet approximately 48" high, 33" deep, and 24" wide, weighing about 55 pounds, with a door opening both inward and outward. In use, the user sat on a stool inside the device and an electric steam generator produced steam through heating a container of water provided inside.

LIBELED: 5–18–65, E. Dist. Va.

CHARGE: 502(a)—when shipped, the labeling of the device, namely, the brochures which accompanied the article, contained false and misleading representations that the article was adequate and effective as a treatment for maintaining normal weight, improving blood circulation, general fatigue, tensions, and aches and pains that may be symptoms of respiratory infections, maintaining excellent mental and physical fitness, for inducing restful, natural sleep, for restoring mental and physical vigor, and that use of the article promoted greater body health, removed skin excreta that caused blackheads and skin blemishes, and that, when using the article, expensive tranquilizers and other habit-forming tension relievers could be a thing of the past.

DISPOSITION: 6–17–65. Consent—claimed by Henry A. Demar, Arlington, Va. Brochures ordered destroyed, and the devices to be relabeled.

8498. **McKune Whirlpool Bath device.** (F.D.C. No. 50694. S. No. 56–305 A.)

QUANTITY: 6 devices at Omaha, Nebr.

SHIPPED: 7–10–64, from Chicago, Ill., by John J. McKune & Sons Co., Inc.

LABEL IN PART: (Front of device) "McKune Whirlpool Bath" and (shipping ctn.) "John J. McKune & Sons Co. Inc. Whirlpool Bath Unit * * * Omaha, Nebraska."

ACCOMPANYING LABELING: Leaflets entitled "Whirlpool Hydromassage," "Whirlpool Hydrotherapy," and "Arthritis—Poor Circulation—Tension—Headaches"; counter cards entitled "Ask For A Room with Whirlpool Massage," "Tension Stress Nerves on Edge Can't Sleep?" and "McKune Home Whirlpool Hydromassage Bath Unit"; copy of page from the Journal of American Medical Association, 10–12–63; and copies of letters to John J. McKune & Sons Co., Inc., from R. R. Eisenberg (dated 11–19–63), Mrs. John Gross (undated), and I. Simon (dated 11–18–63).

RESULTS OF INVESTIGATION: Examination indicated that the device consisted of an electric motor which forced air through a plastic tube attached to a perforated metal pipe, which pipe fitted into and around the bottom of a bathtub. The air which was forced through the perforated pipe agitated the water, causing it to become turbulent in order to effect an alleged therapeutic motion.

LIBELED: On or about 11–1–64, Dist. Nebr.; libel amended on or about 12–1–64.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for aches and pains, impaired circulation, to break down all hardened inflammatory deposits, loosen joints, limbs darkened by stagnation, arthritis, nervous tension, headaches, weight and posture control, slipped disc, and aching back.

DISPOSITION: 12–21–64. Default—delivered to a charitable institution.

8499. Selectronair air purifier device. (F.D.C. No. 51391. S. No. 45–010 B.)

QUANTITY: 80 individually ctnd. devices at Boston, Mass.

SHIPPED: 4–7–65, and on subsequent dates, from Shelton, Conn., by The Wiffle Ball, Inc.

LABEL IN PART: (Metal plates on device) "Selectronair" and "Model 1 * * * Mfd. by The Shelton Metal Products Co., Inc. Shelton, Conn."; (ctn.) "Selectronair Air Purifier * * * Distributed by."

ACCOMPANYING LABELING: Leaflets entitled "Operating Instructions," Selectronair Air Sanitizer Parts List," and undetermined quantities of leaflets entitled "Selectronair Selects and Sanitizes the Air You Breathe NOW . . . germ-free air in every corner of any room"; and an unknown number of newspaper tear sheets of advertisements from both the Boston Globe and the Boston Herald of April 18, 1965.

RESULTS OF INVESTIGATION: The literature indicated the article to be an air circulator made of a motor and two centrifugal blowers. Associated with each blower was a filter and three ultraviolet lamps. Air was pulled through the filter, irradiated with ultraviolet and blown out through a directionally controlled exhaust portal.

LIBELED: 5–17–65, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the leaflets and newspaper tear sheets, contained false and misleading representations that the article was adequate and effective as a treatment for relieving hay fever, pollen irritation and pollen asthma, sinus congestion, most respiratory ailments and conditions, allergies, reducing colds, sore throats, preventing cross contamination of respiratory conditions, and destroying airborne bacteria associated with the common cold, preventing sore throats, and for providing germ-free air in every corner of any room.

DISPOSITION: 6–22–65. Consent—claimed by The Wiffle Ball, Inc., Shelton, Conn., for relabeling.

8500. Mamco Electronic Air Cleaner device. (F.D.C. No. 50830. S. No. 27–293 A.)

QUANTITY: 5 devices at Glen Ellyn and Libertyville, Ill.

SHIPPED: 10–6–64, from Racine, Wis., by Mamco Corp., Electronic Div.

LABEL IN PART: "Mamco Electronic Air Cleaner * * * Serial * * * Mfg. by Mamco Corporation Electronic Air Cleaner Mamco."

ACCOMPANYING LABELING: Folders entitled "Breathe clean, pure fresh air with . . . Mamco Electronic–Air–Cleaner"; booklets entitled "Facts About Mamco Air Cleaner"; leaflets entitled "Mamco Air Cleaner collects pollen, dust, smoke, odors"; and pamphlets entitled "Electronic Air Cleaners for Residential Installation."

RESULTS OF INVESTIGATION: The accompanying labeling indicated the article to be an electrically-operated air cleaning unit intended to be connected to circulating air heating or cooling systems. Depending upon the models involved, the units had a total weight of from 55 to 122 pounds and had a power consumption of approximately 10 watts at 115 volts a.c. Each unit was enclosed in a 22-gauge epoxy-enameled steel cabinet and contained aluminum filter frames and filter elements. Charcoal filters were optional.

LIBELED: 11–25–64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for hay fever, dust allergies, burning eyes, headaches, sneezing, choked-up feeling, and that use of the article would clean up all of the many thousands of large as well as tiny airborne particles that contaminate the air you breathe.

DISPOSITION: 1–18–65. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 8441 TO 8500

PRODUCTS

[1] (8452, 8461, 8488, 8494) Seizure contested.
[2] (8469) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8452, 8461, 8488, 8494) Seizure contested.
[2] (8469) Injunction issued.

[1] (8452, 8461, 8488, 8494) Seizure contested.
[2] (8469) Injunction issued.

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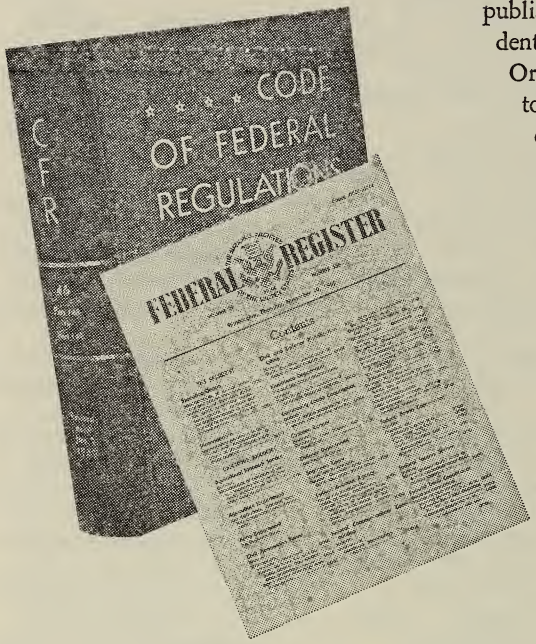

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D.D.N.J., F.D.C. 8501–8560 Issued September 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8501–8560

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, including, in one case, the entry of a consent decree of permanent injunction; (2) a criminal proceeding which was terminated upon a plea of guilty; and (3) an injunction proceeding in which a decree of permanent injunction was entered. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

In addition, there is also reported an injunction proceeding instituted by owners of devices which were alleged to be misbranded, and which proceeding was terminated by the court's dismissal of the action.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *September 19, 1966.*

CONTENTS*

*For drug without assurance of current good manufacturing practice, see No. 8503; drug processed in an establishment not duly registered under the Act, No. 8505; omission of, or unsatisfactory, ingredients statements, No. 8509; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 8540, 8546; cosmetics, subject to the drug provisions of the Act, Nos. 8534, 8557–8559.

228-098—66——1

SECTIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8501–8560

Adulteration, Section 501(a)(2)(B), the article was a drug and the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice to assure that such drug met the requirements of the Act as to safety, and had the identity and strength, and met the quality and purity characteristics, which it purported to be and was represented to possess; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia, National Formulary), and its strength differed from or its quality or purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(e)(1)(A)(i), the article was a drug, and its label failed to bear the established name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 502(o), the article was a drug, and it was manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered under Section 510.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an approval of an application filed pursuant to Section 505(b) was not effective with respect to such drug.

Failure to register, Section 510, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing, of a drug or drugs shall, upon first so engaging and on or before December 31 of each year, register with the Secretary, his name, places of business and all such establishments.

Refusal to permit entry or inspection, Section 704, for purposes of enforcement of this Act, officers or employees duly designated by the Secretary are authorized to enter and inspect any factory, warehouse, or establishment in which drugs are manufactured, processed, packed, or held for introduction into interstate commerce, or after such introduction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8501. Dipyrone injections. (F.D.C. No. 51393. S. Nos. 21–464/6 B.)

QUANTITY: 51 individually ctnd. 30-cc. vials, 33 individually ctnd. 10-cc. vials, and 45 30-ml. vials, at Tulsa, Okla.

SHIPPED: 11–26–63, the 30-ml. vials from Oceanside, N.Y., by Lambda Pharmacal Laboratories, Inc., and during 1959, the 10-cc. and 30-cc. vials from Los Angeles, Calif.

LABEL IN PART: (30-ml. vial and ctn.) "30 ml. * * * Lambda Dipyrone Injection 50% * * * Lambda Pharmacal Laboratories, Inc. Oceanside, N.Y."

LIBELED: 5–20–65, N. Dist. Okla.

CHARGE: The article in the 30-ml. vials was misbranded when shipped, and the article in the 10-cc. and 30-cc. vials was misbranded while held for sale, as follows:

502(f)(1)—the labeling failed to bear adequate directions for use and the articles were not exempt from such requirement, since the labeling failed to bear, as required by regulations, adequate information for their use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drug safely and for the purposes for which they were intended, including all the purposes for which they were advertised or represented in their labeling; and 502(j)—the articles were dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, or suggested in their labeling.

DISPOSITION: 7–13–65. Default—destruction.

8502. Key-Pyrone liquid. (F.D.C. No. 49905. S. No. 86–524 A.)

QUANTITY: 67 cases, each containing 12 1-pt. btls., at Memphis, Tenn.

SHIPPED: 11–27–63, from St. Louis, Mo., by E. W. Heun Co.

LABEL IN PART: (Btl.) "Key-Pyrone Liquid Each teaspoonful (5 cc) contains: Dipyrone (Methampyrone Sodium)____ 0.5 gm. * * * Caution * * * Manufactured for Key Pharmacal Co. Memphis, Tenn. See insert."

ACCOMPANYING LABELING: Package insert entitled "Key-Pyrone Analgesic–Antipyretic."

LIBELED: 3–9–64, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article had a wide range of usefulness and was indicated as an analgesic and antipyretic because of the absence of serious untoward effects; 502(j)—the article was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement, since the article was a prescription drug and its labeling failed to conform to the requirements of regulations which provide that the labeling bear adequate information for its use, including dosages, frequency and duration of administration, and relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to administer the drug could use the drug safely and for the purposes for which it was intended.

DISPOSITION: 12–2–64. Consent—claimed by Key Pharmacal Co., Memphis, Tenn., for relabeling.

8503. Bacitracin ophthalmic ointment. (F.D.C. No. 50865. S. No. 85–908 A.)

QUANTITY: 168 1-tube cases at Philadelphia, Pa.

SHIPPED: 9–8–64, from East Paterson, N.J., by Biocraft Laboratories, Inc.

LABEL IN PART: (Tube) "Bacitracin Ophthalmic Oinment U.S.P. 1/8 oz. (3.54 Gm.) Each Gm. contains: Bacitracin 500 Units in a Mineral Oil U.S.P. and Petrolatum U.S.P. base * * * Distributed by Harvey Laboratories, Inc., Philadelphia 44, Pa."

Results of Investigation: Examination showed that the article contained metal fragments. Inspection of Biocraft Laboratories, Inc., on 9–18/21–64, disclosed that the metal tubes in which the article was packed contained metal fragments when received from the tube manufacturer and that Biocraft Laboratories, Inc., had attempted to remove such particles by use of a vacuum device which was designed only to remove lint.

Libeled: 12–7–64, E. Dist. Pa.

Charge: 501(a)(2)(B)—when shipped, the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding, did not conform to, and were not operated and administered in conformity with, current good manufacturing practice to assure that the article met the quality and purity characteristics which it purported and was represented to possess; 501(b)—the article purported to be and was represented as a drug, "Bacitracin Ointment," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the standard set forth in such compendium; 502(a)—the label statement "Bacitracin * * * Ointment U.S.P." was false and misleading as applied to a product which does not conform to the standard set forth in the United States Pharmacopeia for such product; and 502(j)—the article was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof.

Disposition: 1–27–65. Default—destruction.

8504. Burdick Rythmic Constrictor device. (F.D.C. No. 51530. S. No. 14–969 B.)

Quantity: 25 devices at Los Angeles, Calif., in possession of Abbey Rents.

Shipped: On unknown dates approximately 18 to 20 years ago, from Milton, Wis.

Label in Part: (Metal plate on front of devices) "Burdick Rythmic Constrictor"; (metal plate on back of device) "Burdick RC–2 [or "RC–1"] * * * The Burdick Corporation, Milton, Wis."; (sticker label on back of device) "Warning This Physical Therapy Equipment is Dangerous to Health Unless Established, Safe Factors are Observed. Sold To Be Used Only By Or On The Prescription Of A Physician, Dentist or Veterinarian. Manufactured by The Burdick Corp. Milton, Wis."; and (tag on device) "Electrically operated * * * Used in Treatment of Vascular Diseases."

Accompanying Labeling: Leaflet entitled "Therapeutic Lamps * * * Electrical Apparatus * * * Burdick Constrictor Used in treatment of vascular diseases."

Results of Investigation: Inspection indicated that the device consisted of a cabinet which contained an air compressor, pressure gauge, timers, valve and pressure control for applying air pressure to a cuff attachment around the limbs of a patient. Accompanying labeling was used in promoting sales of the article by the dealer.

Libeled: 7–26–65, S. Dist. Calif.

Charge: 502(a)—while held for sale, the labeling of the article, namely, the tag on the device and the leaflet described above, contained false and misleading representations that the article was adequate and effective as a treatment for vascular diseases; 502(f)(1)—the labeling failed to bear adequate directions for use, and adequate directions for use in the treatment of vascular

diseases could not be written, since the device was without value for such purpose, and it was not exempt from those requirements, since it was a prescription device and it was not labeled in accordance with the labeling requirements of the regulations; and 502(j)—the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in the labeling thereof.

DISPOSITION: 8–23–65. Default—2 devices were delivered to the Food and Drug Administration and the remaining devices were destroyed.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

8505. Meprobamate. (Inj. No. 487.)

COMPLAINT FOR INJUNCTION FILED: 3–26–64, Dist. N.J., against Jobar Chemicals, Inc., Sayreville, N.J., and Frank Alberte, manager.

NATURE OF BUSINESS: The defendants were alleged to be engaged in manufacturing, processing, packing, labeling, promoting, selling, and distributing a drug designated as "*meprobamate*" which was fabricated from various ingredients of which two ingredients, namely, urethane and aluminum isopropylate, were shipped in interstate commerce, into the State of New Jersey.

CHARGE: The complaint alleged that the drug, if introduced into interstate commerce, would be in violation of 505(a), since it was a new drug for which no approval of a new-drug application was effective, and that the drug would also be misbranded under 502(o), since it was manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered under the Act.

The complaint alleged further that the acts of the defendants in manufacturing, preparing, and processing the drug in an unregistered establishment resulted in the drug being misbranded while held for sale after shipment in interstate commerce.

The complaint alleged also that, on 3–24–64, an inspector of the Food and Drug Administration had presented to the defendant, Frank Alberte, during ordinary business hours, appropriate credentials and a written notice to enter and inspect the defendant's business premises and that the defendant had refused to permit the inspector to enter and inspect such premises.

DISPOSITION: On 3–26–64, the court entered a temporary restraining order enjoining the defendants from the acts complained of. The defendants filed an answer and thereafter advised the court that they did not wish to contest the action further. On 5–15–64, a decree of permanent injunction was entered which perpetually enjoined and restrained the defendants from directly doing or causing to be done any of the following acts

(1) engaging in the manufacture, preparation, propagation, compounding, processing, or distributing of *meprobamate*, or any other drug, in establishments owned or operated by the said defendants, unless and until the said corporate defendant registered with the Secretary of Health, Education, and Welfare, its name, including the name of each officer and director and the State of incorporation, its places of business, and all its establishments which are engaged in the manufacture, preparation, propagation, compounding, or processing of *meprobamate*, or any other drug, and permitted entry into and inspection of each such establishment;

(2) introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and holding or causing to be held after shipment in interstate commerce, the article of drug designated as "*meprobamate*," or any other drug, which has been, is, or will be manufactured, prepared, propagated, compounded, or processed in the establishment which is not registered with the Secretary of Health, Education, and Welfare;

(3) introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the article of drug designated as "*meprobamate*," or any other new drug, unless and until an approval of a new-drug application filed pursuant to 505 is effective with respect to such drug;

(4) refusing to permit entry into and inspection by Food and Drug inspectors of each establishment owned or operated by defendants in which drugs are manufactured, processed, packed, or held.

The decree provided also that the *meprobamate* manufactured by the defendants, together with the raw materials used in its manufacture, should be destroyed by the defendants under the direct supervision of a representative of the Food and Drug Administration.

8506. Tega-Pyrone liquid and tablets. (F.D.C. No. 51116. S. Nos. 30–907/12 B.)

QUANTITY: 21 cases, each containing 20 16-oz. btls., plus 176 16-oz. btls., 69 1-oz. btls., and 12 1-gal. btls., of *Tega-Pyrone liquid*, and 10 cases, each containing 12 100-tablet btls., 2 cases, each containing 12 100-tablet btls., plus 69 100-tablet btls., and 28 100-tablet btls., of *Tega-Pyrone tablets*, at Jacksonville, Fla.

SHIPPED: Between 10–10–62 and 4–29–64, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Btls.) "Tega-Pyrone Liquid Each 5 cc contains: Dipyrone 125 mgm. Isopropyl Phenazone 125 mgm. * * * Caution: Federal law prohibits * * * Indications: for use in acute pain, when both rapid and prolonged action are desired * * * Usual Dose * * * Precautions: * * * Contraindications * * * Manufactured for Ortega Pharmaceutical Company, Inc. Jacksonville 5, Florida," and "Tega-Pyrone Tablets Each tablet contains: Dipyrone 125 mgm. Isopropyl Phenazone 125 mgm. Caution: Federal law prohibits * * * Usual Dose: 1 tablet * * * Caution * * * Manufactured for Ortega Pharmaceutical Company, Inc. Jacksonville 5, Florida."

ACCOMPANYING LABELING: Some of the tablet bottles had an insert reading in part "Precautions * * * Contraindications * * * Indications."

LIBELED: 3–23–65, M. Dist. Fla.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drugs.

DISPOSITION: 4–8–65. Default—destruction.

8507. Laetrile. (F.D.C. No. 50942. S. No. 19–001 B.)

QUANTITY: 5 boxes of 10 vials each, at Boise, Idaho.

SHIPPED: 1–28–65, from San Francisco, Calif., by Krebs Laboratories.

LABEL IN PART: (Vial) "Laetrile Cyanide Glucoside 2000 mgs. Type Amygdain Lyophilized Krebs Laboratories, San Francisco, Calif. * * * Not for oral administration * * * Caution: Federal law prohibits dispensing without prescription."

ACCOMPANYING LABELING: Literature entitled "Laetrile, Directions for the Administration of," "Laetrile," "Neitrioside foods," and "Sigmoid Laetrile Instillation."

LIBELED: 2–5–65, Dist. Idaho.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 4–30–65. Default—delivered to the Food and Drug Administration.

8508. Viril-Lam tablets. (F.D.C. No. 50914. S. No. 84–067 A.)

QUANTITY: 536 individually ctnd. 25-tablet btls., at Caparra Terrace (San Juan), P.R.

SHIPPED: Between 8–20–64 and 10–15–64, from Long Island, N.Y., by Lambda Pharmacal Laboratories, Inc.

LABEL IN PART: (Btl.) "Viril-Lam Caution—Lambda Pharmacal Laboratories, Inc., Oceanside, New York—Each tablet supplies methyltestosterone USP 10 mg. pituitary extract anterior lobe 4 mg. Adrenals 4 mg. Yohimbine HCl 5 mg. Vitamin A 5000 USP Units, Vitamin E 1 mg. Vitamin B_1 5 mg. Zinc Phosphide 1.5 mg. Strychnine Sulfate 0.05 mg.—Dosage 3 tablets daily."

LIBELED: 2–11–65, Dist. P.R.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 4–8–65. Default—destruction.

8509. Unitroid capsules. (F.D.C. No. 50959. S. Nos. 119–649/50 A.)

QUANTITY: 144 7-capsule btls., 52 100-capsule btls., and 21 1,000-capsule btls., each individually ctnd., of *Unitroid 100;* and 61 100-capsule btls. and 20 1,000-capsule btls., each individually ctnd., of *Unitroid 200*, at Glendale, Ariz., in possession of Myers-Carter Laboratories, Inc.

SHIPPED: 5–18–64, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl. and ctn.) "Unitroid 100 [or "200"] anorectic * * * Each sustained release capsule contains: l-phenaminopropane succinate 21 mgm. *Mycaloid, U.S.P. 100 mgm. [or "200 mgm."] * * * Myers-Carter Laboratories, Inc. Phoenix, Arizona * * * Caution: Federal law prohibits * * * Dosage: Usually one capsule daily upon arising. *Mycaloid is Myers-Carter's brand of specially processed, desiccated and de-fatted pork thyroid * * * Indications: For use as an appetite suppressant and metabolic stimulant."

RESULTS OF INVESTIGATION: The articles were shipped in bulk lots and repacked by the dealer into the bottles described above.

LIBELED: 1–4–65, Dist. Ariz.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drugs; and 502(e)(1)(A)(i)—while held for sale, the articles were fabricated from two or more ingredients and their labels failed to bear the established

name of the active ingredient "l-amphetamine succinate" in place of the name "l-phenaminopropane succinate."

DISPOSITION: 3–5–65. Default—destruction.

8510. Papavatral L.A. capsules. (F.D.C. No. 50848. S. Nos. 79–556/7 A.)

QUANTITY: 23 250-capsule btls. and 61 30-capsule btls. at Hackensack, N.J.

SHIPPED: Between 9–24–64 and 11–19–64, from New Rochelle, N.Y., by Kenwood Laboratories, Inc.

LABEL IN PART: (Btl.) "Papavatral L.A. Continuous Controlled Release Each Capsule contains: Ethylpapaverine HCl (Ethaverine Hydrochlor.) 30 mg. Pentaerythritol tetranitrate 50 mg. Kenwood Laboratories, Inc. New Rochelle, N.Y. Indications: Angina pectoris, hypertensive states * * * Dosage: One capsule in morning and one capsule in evening. Caution: Federal Law Prohibits."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately the declared amounts of ethaverine hydrochloride and pentaerythritol tetranitrate.

LIBELED: 1–7–65, Dist. N.J.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 2–25–65. Default—destruction.

8511. Garcels Formulas. (F.D.C. No. 50125. S. Nos. 49–585/7 A.)

QUANTITY: 4 cases, each containing 12 1,000-capsule btls. of *Garcels Formula M–22*, 11 1,000-tablet btls. of *Garcels Formula M–31*, and 3 cases, each containing 12 1,000-tablet btls., plus 8 additional btls., *Garcels Formula M–30*, at South Bend, Ind.

SHIPPED: (*Formula M–22 capsules*) 11–30–60, from Long Island City, N.Y., by Nysco Laboratories, Inc.; (*Formula M–31 tablets* and *Formula M–30 tablets*) 4–19–63 and 10–14–63, from Elgin, Ill., by Standard Pharmacal Corp.

LABEL IN PART: (Btl.) "Garcels Formula M–22 Each Capsule Contains * * * Directions For Use: As a dietary supplement in the treatment of Liver Disease associated with Lipid Metabolism * * * Distributed by the Garland Co., Inc., South Bend 24, Indiana," "1000 Tablets Garcels Formula M–31 Each Tablet Contains: * * * Menadione 0.33 mg. * * * Distributed by Garland Pharmaceuticals, Inc. South Bend 24, Indiana," and "1000 Tablets Garcels Formula M–30 Each Tablet Contains * * * Menadione 0.33 mg. * * * Distributed by Garland Pharmaceuticals, Inc. South Bend 24, Indiana."

LIBELED: 5–15–64, N. Dist. Ind.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drugs.

Formula M–22 capsules, 502(f)(1)—when shipped, the label of the article failed to bear adequate directions for use in the treatment of liver disease associated with lipid metabolism.

DISPOSITION: 12–31–64. Consent—destruction.

8512. Doloronil capsules. (F.D.C. No. 50397. S. Nos. 12-565/6. A.)

QUANTITY: 432 100-capsule btls., and approximately 250 capsules in a 1,000-capsule btl., at Shelton, Conn.

SHIPPED: 5-21-63 and 5-28-63, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Btl.) "Doloronil Each Capsule Contains: Isopropyl Phenazone 65 mgm. Salicylamide 227 mgm. (3½ grs.) Phenacetin 162 mgm. (2½ grs.) Caffeine 32.4 mgm. (½ gr.) * * * Manufactured for Haddad Pharmaceutical Co. Shelton, Conn. * * * 1 capsule three times daily * * * Caution: Federal law prohibits" and (pkg. insert) "Doloronil Indications * * * Side Effects."

LIBELED: 7-28-64, Dist. Conn.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 10-14-64. Default—destruction.

8513. Marla contact lens wetting solution. (F.D.C. No. 50777. S. Nos. 129-326/7 A.)

QUANTITY: 68 4-oz. btls. at Dayton, Ohio.

SHIPPED: 10-23-64 and 11-1-64, from Buffalo, N.Y., by Santa Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Marla Antiseptic Wetting and Soaking Solution For Contact Lenses * * * Bacteriacidal Fungicidal * * * Contains: Phenoxynate Manufactured In U.S.A. By Santa Pharmaceuticals, Inc., Buffalo 16, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable micro-organisms.

LIBELED: 12-17-64, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it was purported and represented to possess; 502(a)—the label statements "Antiseptic" and "Bacteriacidal" were false and misleading; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 2-15-65. Default—destruction.

8514. Marla contact lens wetting solution. (F.D.C. No. 50918. S. No. 103-200 A.)

QUANTITY: 2 cases of 144 4-oz. btls. at Buffalo, N.Y.

SHIPPED: 12-17-64, from Portland, Oreg. This was a return shipment.

LABEL IN PART: (Btl.) "Marla Antiseptic Wetting And Soaking Solution For Contact Lenses * * * Bacteriacidal * * * Contains: Phenoxynate Manufactured in U.S.A. By Santa Pharmaceuticals, Inc., Buffalo 16, N.Y."

LIBELED: 1-11-65, W. Dist. N.Y.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it was purported and represented to possess; 502(a)—the label statements "Antiseptic" and "Bacteriacidal" were false and misleading as applied to a product which was contaminated with viable micro-organisms; and 505(a)—the article was a new drug which may not be introduced or

delivered for introduction into interstate commerce, since no approval of an application was effective with respect to such drug.

DISPOSITION: 3–3–65. Default—destruction.

DRUGS FOR VETERINARY USE

8515. **Dymasol.** (F.D.C. No. 50740. S. No. 42–976 A.)

QUANTITY: 9 12-oz. btls. at Littleton, Colo.

SHIPPED: 9–10–64, from Hialeah, Fla., by Zirin Laboratories International, Inc.

LABEL IN PART: "Dymasol Contains Dymasol (Brand of) Dimethyl Sulfoxide Limited by Federal Law for Animal and Laboratory Tests * * * Indications * * * Directions * * * Use Only * * * Distributed by International, Inc., Miami 48, Florida."

LIBELED: 11–18–64, Dist. Colo.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drug and it was not exempt since it did not comply with the regulations regarding new drugs for investigational use.

DISPOSITION: 12–30–64. Default—destruction.

8516. **Dymasol (2 seizure actions).** (F.D.C. Nos. 50938; 50990. S. Nos. 40–282 B; 22–861 B.)

QUANTITY: 28 1-pt. btls. at Metairie, La.; and 44 1-pt. btls. at Houston, Tex.

SHIPPED: 10–26–64 and 11–17–64, from Hialeah, Fla., by Zirin Laboratories International, Inc.

LABEL IN PART: "Dymasol Contains: Dimethyl Sulfoxide—80% * * * Limited by Federal Law For Animal and Laboratory Tests [or "For Veterinary Use Only For Experimental Use Only"] * * * Distributed by Zirin Laboratories Int'l., Inc. Miami 48, Florida."

LIBELED: 1–29–65, E. Dist. La.; and 2–2–65, S. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drug and it was not exempt since it did not comply with the regulations with respect to new drugs for investigational use.

DISPOSITION: 3–11–65 and 3–5–65. Default—destruction.

8517. **Dymasol.** (F.D.C. No. 50940. S. No. 40–281 B.)

QUANTITY: 28 12-oz. btls. at New Orleans, La.

SHIPPED: Prior to 10–4–64, from Hialeah, Fla., by Zirin Laboratories International, Inc.

LABEL IN PART: "Dymasol Contains Dymasol (Brand Of) Dimethyl Sulfoxide Limited By Federal Law for Animal and Laboratory Tests * * * Indications: For Pain, Soreness And Inflammation * * * For Veterinary Use Only For Experimental Use Only * * * Distributed by Zirin Laboratories Int'l., Inc., Miami 48, Florida."

LIBELED: 1–29–65, E. Dist. La.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drug and it was not exempt from such requirement, since it did not comply with the regulations applicable to drugs for investigational use.

DISPOSITION: 3–11–65. Default—destruction.

8518. Dymasol. (F.D.C. No. 50939. S. No. 1–606 B.)

QUANTITY: 9 1-pt. btls. at Barnesville, Ohio.

SHIPPED: 12–21–64, from Muncie, Ind., by Pearson's Harness Horse Equipment Co.

LABEL IN PART: "Dymasol Contains: Dimethyl Sulfoxide 80% * * * Indications: For Pain, Soreness and Inflammation * * * For Veterinary Use Only For Experimental Use Only * * * Distributed by Zirin Laboratories Int'l., Inc., Miami 48, Florida."

LIBELED: 1–28–65, S. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drug and it was not exempt from such requirement, since it did not comply with the regulations relating to drugs for investigational use.

DISPOSITION: 5–17–65. Default—destruction.

8519. Butasave liquid and phenylbutazone tablets. (F.D.C. No. 50997. S. Nos. 5–836/7 A.)

QUANTITY: 24 50-cc. individually ctnd. vials and 6 100-tablet btls., at Gainsville, Fla.

SHIPPED: Between 10–20–64 and 1–31–65, from Canada, by Zirin International Laboratories.

LABEL IN PART: (Vial and ctn.) "Butasave For Veterinary Use Only Phenylbutazone Distributed by Zirin Laboratories Int'l., Inc. Miami 48, Fla.," and (btl.) "Phenylbutazone V.C.T. 1 Gm. Tablets For Veterinary Use Only * * * 6178 Distributed by Zirin Laboratoris Int'l., Inc. Miami 48 Florida."

LIBELED: On or about 2–3–65, N. Dist. Fla.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drugs.

DISPOSITION: 3–16–65. Default—destruction.

8520. Medical Fluid 360. (F.D.C. No. 51125. S. Nos. 61–728/9 A.)

QUANTITY: 3 40-lb. drums, 4 unlabeled 1-lb. btls., and 1 1-lb. labeled btl., at Los Angeles, Calif.; and 6 unlabeled 1-gal. containers, at Beverly Hills, Calif.

SHIPPED: Between 8–14–64 and 10–16–64, from Midland, Mich., by Dow Corning Corp.

LABEL IN PART: (Drum) "Dow Corning 360 Medical fluid * * * Ingredients: A dimethylpolysiloxane fluid. Caution: For manufacturing * * * Made by Dow Corning Corporation Medical Products Division Midland. Michigan * * * Caution: New Drug Limited by Federal Law to Laboratory Studies and tests on animals. Not for human use," and (btl.) "Dow Corning Medical

Fluid * * * Caution—New Drug. Limited By Federal Law To Lab Studies And Tests on Animals. Not For Human Use Garfield Prescription Pharmacy * * * Los Angeles."

RESULTS OF INVESTIGATION: The lot at Los Angeles had been shipped in bulk drums and had been repacked in part by the Garfield Prescription Pharmacy, into the 1-lb. bottles described above. The lot at Beverly Hills had also been shipped in bulk drums and had been repacked by Harvey D. Kagan, M.D., into 1-gal. containers.

Portions of both lots had been used for injection into humans and there was no reason to believe that the remainder of the lots was not so intended for such use.

LIBELED: 3–24–65, S. Dist. Calif.

CHARGE: All lots, 505(a)—the article was a new drug which may not be introduced or delivered into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug, and it was not exempt, since it did not comply with the regulations with respect to new drugs for investigational use.

40-lb. drums, 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use and it was not exempt from such requirement, since it failed to comply with the conditions for exemption prescribed by regulations with respect to a drug in a bulk package intended for processing, repacking, or use in the manufacture of another drug.

DISPOSITION: 4–16–65. Default—destruction.

8521. Animal Vet-Tox. (F.D.C. No. 50855. S. No. 15–578 A.)

QUANTITY: 1 55-gal. drum containing approximately 40 gals., and 26 repacked 1-pt. btls., at Franklin, Mass.

SHIPPED: 7-23-64, from North Providence, R.I., by White Cross Chemicals.

LABEL IN PART: (Btl.) "Animal Vet-Tox * * * For Foot Rot (Porodermatitis) Thrust Ring Worm * * * Active Ingredients: Copper Naphthenate 38% * * * Manufactured for Vet-Med Supply Co. 29 Dean Avenue, Franklin, Mass."

RESULTS OF INVESTIGATION: The article was repacked by the dealer, into pint bottles described above, with labels being furnished by White Cross Chemicals.

LIBELED: 11-30-64, Dist. Mass.; libel amended 12-7-64.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to the law was effective with respect to such drug.

DISPOSITION: 4-20-65. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

8522. Vit-Ra-Tox products. (F.D.C. No. 49872. S. No. 33–221 X.)

INFORMATION FILED: 6–30–64, Dist. Minn., against Margaret Syring., St. Paul, Minn.

ALLEGED VIOLATION: On 7–2–63, while the article described below was held for sale after shipment in interstate commerce, the defendant caused the article to

*See also Nos. 8501, 8502, 8504, 8511.

be offered for sale and sold for use of various diseases, symptoms, conditions, and purposes, which act resulted in the drug being misbranded.

LABEL IN PART: "No. 19 Colo-Clenz Intestinal Cleanser [or "Vit-Ra-Tox '16' An Adsorbent Aid," or "Vit-Ra-Tox No. 21 A A Dietary Supplement," or "Vit-Ra-Tox #48 * * * Whole Beet Juice," or "Vit-Ra-Tox No. 19 A Herb Tablets"] V. E. Irons Inc. Boston 15, Mass."

ACCOMPANYING LABELING: Booklets entitled "What is Toxemia?" and "Medicinal Value of Natural Foods"; leaflets entitled "Regimen for Cleansing and Rebuilding with Greenlife Products," "Veico (Bentonite) Systemic Detoxifier," "Greenlife—What is Greenlife?" and "Checking Procedures for Doctors Using Springreen"; and reprints of a letter, dated 1–17–56, bearing the letterhead of Hasty Heart Clinic.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the "Greenlife Program," consisting of the components listed above, was adequate and effective for the treatment and prevention of toxemia, colds, flu, pneumonia, typhoid fever, tuberculosis, asthma, bronchitis, hypothyroidism, rheumatism, diabetes, jaundice, insomnia, nervousness, syphilis, constipation, lumbago, hardening of the arteries, dropsy, prostatitis, anemia, skin eruptions, poor complexion, brain fag, dyspepsia, gout, obesity, cystitis, gonorrhea, pyorrhea, catarrh, gallstones, worms, halitosis, goiter, impotence, piles, stomach ulcers, low blood pressure, biliousness, low vitality, poor circulation, emaciation, hepatitis, cancer, migraine, polio, high blood pressure, neurasthenia, inflammations and malignancies of the digestive tract, sore throat, gastritis, colon ulcers, appendicitis, nephritis, lymphangitis, epilepsy, sciatica, arteriosclerosis, and cinchonism; and 502(f)(1)—the labeling failed to bear adequate directions for use for the diseases, symptoms, conditions and purposes, for which the article was intended, offered for sale, and sold, namely, to remove cholesterol from the arteries, cleanse the whole body, cleanse and rebuild the bones, absorb poisons in the body, for the treatment and prevention of Bright's disease, kidney disease, liver disease, edema, swollen legs and body, bad heart, colon trouble, falling hair, baldness, weak eyes, decaying teeth, wrinkled skin, arthritis, heart disease, cancer of the bone, cancer of the internal organs, rheumatic fever, Parkinson's disease, enlarged thyroid gland, leukemia, indigestion, pinworms, tapeworms, warts, body sores, itching, burning skin, pimples, oozing skin eruptions, kidney stones, gallstones, bladder stones, tumors, liver conditions, heart conditions, blood conditions, cramps, heart attacks, children's diseases, cataracts, varicose veins, stroke, hemorrhoids, and hay fever; for the diseases, symptoms and conditions represented by the claim that the article of drug would "cure anything"; toxemia, colds, flu, pneumonia, typhoid fever, tuberculosis, asthma, bronchitis, hypothyroidism, rheumatism, diabetes, jaundice, insomnia, nervousness, syphilis, constipation, lumbago, hardening of the arteries, dropsy, prostatitis, anemia, skin eruptions, poor complexion, brain fag, dyspepsia, gout, obesity, cystitis, gonorrhea, pyorrhea, catarrh, gallstones, worms, halitosis, goiter, impotence, piles, stomach ulcers, low blood pressure, biliousness, low vitality, poor circulation, emaciation, hepatitis, cancer, migraine, polio, high blood pressure, neurasthenia, inflammations and malignancies of the digestive tract, sore throat, gastritis, colon ulcers, appendicitis, nephritis, lymphangitis, epilepsy, sciatica, arteriosclerosis, and cinchonism.

PLEA: Guilty.

DISPOSITION: 9–28–64. $250 fine.

8523. **Y-Tempernil liquid.** (F.D.C. No. 50319. S. No. 72–777 A.)

QUANTITY: 187 pt. btls. and 16 gal. btls. at New Albany, Miss.

SHIPPED: On unknown dates, from St. Louis, Mo., by E. W. Heun.

LABEL IN PART: (Btl.) "Y-Tempernil Liquid Analgesic Antipyretic Each 5 cc (one teaspoonful) contains: Methampyrone Sodium 500 mg. Caution * * * Manufactured for Y-Laboratories New Albany, Miss. * * * for relief of neuralgia, rheumatic conditions, severe headache, lumbago, biliary and renal colic, colds, influenza, and whenever reduction of fever is desirable Dosage."

LIBELED: 7–6–64, N. Dist. Miss.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 1–18–65. Default—destruction.

8524. **Y-Tempernil tablets.** (F.D.C. No. 50317). S. No. 72–778 A.)

QUANTITY: 181 100-tablet btls. and 51 500-tablet btls. at New Albany, Miss.

SHIPPED: Between 8–1–63 and 6–23–64, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Btl.) "Y-Tempernil Caution * * * Distributed by Y-Laboratories New Albany, Miss. Each Tablet Contains Dipyrone 500 mg. Dose * * * See enclosed literature Control No. 1309."

RESULTS OF INVESTIGATION: Examination showed that no literature was enclosed.

LIBELED: 7–6–64, N. Dist. Miss.

CHARGE: 502(f)(1)—when shipped, labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 1–18–65. Default—destruction.

8525. **Dipyrone injection.** (F.D.C. No. 50318. S. No. 72–779 A.)

QUANTITY: 85 30-cc. individually ctnd. vials at New Albany, Miss.

SHIPPED: Between 2–1–64 and 2–29–64, from Los Angeles, Calif., by Maurry Biological Co., Inc.

LABEL IN PART: (Ctn.) "Multiple Dose Vial Dipyrone 500 mg. per cc. Caution * * * Distributed by Y-Laboratories New Albany, Miss. * * * See Insert," and (insert) "Dipyrone * * * Composition * * * Indications * * * Dosage."

LIBELED: 7–6–64, N. Dist. Miss.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 1–18–65. Default—destruction.

8526. Paradyne dipyrone injection. (F.D.C. No. 50845. S. No. 80–794 A.)

QUANTITY: 94 individually ctnd. vials at Montclair, N.J.

SHIPPED: 8–3–64, from Dayton, Ohio, by Durr Products, Inc.

LABEL IN PART: (Vial and ctn.) "Spanner Injectable #9330 * * * 30 cc. vial Paradyne Dipyrone 0.5 gm. per cc. Analgesic Antirheumatic * * * G. O. Spanner, Inc., Montclair, N.J."

ACCOMPANYING LABELING: Carton insert reading in part "Paradyne Dipyrone Injection Composition * * * Action * * * Indications."

LIBELED: On or about 12–8–64, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling contained statements which represented and suggested that the article was appropriate for the routine treatment of pain associated with neuralgia, rheumatism, lumbago, colic, and pain of infectious disease; and that it was the drug of choice in the treatment of pain; which statements were false and misleading as applied to a product that should have been reserved for use only when other analgesics were not effective and when the risk of fatal agranulocytosis was acceptable; and 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from such requirement, since it was a prescription drug and its labeling failed to bear, as required by regulations, adequate information for its use, including effects and any relevant hazards, contraindications, and side effects, and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 2–23–65. Default—destruction.

8527. Tempyrone Mediserts. (F.D.C. No. 50975. S. No. 37–205 A.)

QUANTITY: 85 boxes, each containing 6 250-mg. Mediserts, and 93 boxes, each containing 6 500-mg. Mediserts, at Houston, Tex., in possession of Medisert Corp. of Texas.

SHIPPED: 7–2–64 and 7–14–64, from Hialeah, Fla., by Pharmaceutical Enterprises, Inc.

LABEL IN PART: (Box) "501A * * * Tempyrone Mediserts * * * Each Medisert contains: Methampyrone 250 mg. [or "500 mg."] Caution: Federal Law prohibits * * * Manufactured for Medisert Corporation * * * Houston, Texas 77001 * * * For rectal administration Only * * * see enclosed package circular * * * Patient instruction sheets enclosed," and (pkg. insert) "Methampyrone Composition And Uses * * * Dose * * * Precautions * * * Contraindications * * * February 1963."

ACCOMPANYING LABELING: Physician's cards entitled "Tempyrone (Anti-Pyretic)."

RESULTS OF INVESTIGATION: The dealer had on hand approximately 350 physician's cards which were printed locally on order of the dealer for the purpose of promoting sales of the article.

LIBELED: 1–14–65, S. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the package insert and the physician's card described above, contained statements which represented and suggested that the article was indicated for symptomatic relief in conditions characterized by pain or fever, including minor injuries such as strains or sprains, headache, dental disorders, and teething problems, which statements were false and misleading, since dipyrone preparations are indicated for antipyretic effect only in serious or life-threatening situations where salicylates or similar drugs are known to be ineffective or not tolerated; and 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from such requirement, since it was a prescription drug and its labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling.

DISPOSITION: 3–2–65. Default—destruction.

8528. Amphetamine sulfate tablets. (F.D.C. No. 48793. S. Nos. 54–706 V, 46–909 X.)

QUANTITY: 40,000 tablets, at Joplin, Mo., in possession of Robert P. Parker.

SHIPPED: On unknown date, from outside the State of Missouri.

LIBELED: On or about 6–11–63, W. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement, since the article was in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage or distribution of prescription drugs.

DISPOSITION: 2–24–65. Default—destruction.

8529. Ethinyl estradiol tablets. (F.D.C. No. 50702. S. No. 61–275 A.)

QUANTITY: 17 1,008-tablet cans at Glendale, Calif.

SHIPPED: 6–26–64, from Dallas, Tex., by Lanpar Co.

LABEL IN PART: (Can) "Lanpar Ethinyl Estradiol * * * Each Tablet Contains: Ethinyl Estradiol U.S.P. 0.015 mg. * * * Lanpar Company * * * Dallas 35, Texas."

ACCOMPANYING LABELING: Inserts entitled "Ethinyl Estradiol * * * Dosage * * * Medical Use * * * Warning * * * Lanpar Co."

RESULTS OF INVESTIGATION: Analysis showed that the article contained not more than 21.3 percent of the declared amount of ethinyl estradiol.

LIBELED: 11–13–64, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, the name of which was recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; 502(a)—the label statement "Each Tablet Contains: Ethinyl Estradiol U.S.P. 0.015 mg." was false and misleading; and 502(f)(1)—the labeling of the article failed to bear adequate directions for

use and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 2–4–65. Default—destruction.

8530. **Formula #1000 tablets.** (F.D.C. No. 50870. S. No. 89–930 A.)

QUANTITY: 7 10,000-tablet boxes and 1 7,500-tablet box, at Fair Winds, Del.

SHIPPED: 7–30–64, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Box) "Zenith Laboratories, Inc., Englewood, New Jersey Formula #1000 Each tablet contains: Methyltestosterone 1.0 mg. Ethinyl Estradiol 0.0006 mg. Vitamin C (Ascorbic Acid) 50 mg. Vitamin B–6 (Pyridoxine HCl) 3.0 mg. For repackaging Use Only * * * Dose * * * Caution: Federal law prohibits."

LIBELED: 12–11–64, Dist. Del.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess since it failed to disintegrate properly; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement, since it was a prescription drug and its labeling failed to bear, as required by regulations, adequate information for its use including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drug safely and for the purpose for which it was advertised or represented in its labeling.

DISPOSITION: 2–8–65. Default—destruction.

8531. **Multiglands injection.** (F.D.C. No. 50910. S. No. 53–833 A.)

QUANTITY: 92 30-cc. vials at Dearborn, Mich.

SHIPPED: 11–5–64, from Philadelphia, Pa., by Vitamix Pharmaceuticals, Inc.

LABEL IN PART: "Multiglands (Plurigland Extract) Intramuscular Only Caution * * * Distributed by Wayne Laboratories, Dearborn, Mich."

LIBELED: 1–5–65, E. Dist. Mich.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 2–3–65. Default—destruction.

8532. **Ray-Pyrine capsules.** (F.D.C. No. 50543. S. No. 87–195 A.)

QUANTITY: 74 1,000-capsule btls., at Philadelphia, Pa., in possession of Raymer Pharmacal Co.

SHIPPED: 11–13–63, from Elgin, Ill.

LABEL IN PART: "Ray-Pyrine Aminopyrine 2½ grs. * * * Usual dose: 1 or 2 capsules * * * Caution: Federal law prohibits * * * Warning * * * Distributed by Raymer Pharmacal Company Philadelphia 34, Pa. Control No."

RESULTS OF INVESTIGATION: The article was repacked by the dealer into the bottles described above.

LIBELED: 8–19–64, E. Dist. Pa.; libel amended 9–10–64.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and it was not exempt from such requirement, since the article was a prescription drug and the labeling failed to bear adequate information for its use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented.

DISPOSITION: 1–27–65. Consent—claimed by Raymer Pharmacal Co. for relabeling.

8533. **Larson's C.R.D.** (F.D.C. No. 50563. S. No. 97–120 A.)

QUANTITY: 259 7½-oz. jars at Fresno, Calif., in possession of Gottschalk's.

SHIPPED: 5–12–64, from Chicago, Ill.

RESULTS OF INVESTIGATION: The dealer intended the article for certain purposes, for which it was not adequate and effective, in an advertisement entitled "New-Easy-Safe Larson's C.R.D. Reducing Diet Plan Helps to Get Slim" that appeared in a local newspaper.

LIBELED: 9–3–64, S. Dist. Calif.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the conditions, purposes, or uses for which it was recommended in a newspaper advertisement, which contained false and misleading representations that the article was adequate and effective to curb the appetite, lose pounds and inches all over the body, promote fitness, health and energy, form bulk and give the feeling of fullness, and to counteract the craving for food.

DISPOSITION: The article was claimed by the Fleetwood Co., who later withdrew its claim and answer, and a decree of condemnation ordering destruction of the article was entered on 1–14–65.

8534. **Sul*Ray Blem-Stick.** (F.D.C. No. 48808. S. No. 40–640 V.)

QUANTITY: 17 display cards, each containing 12 metal tubes, and approximately 70 tubes not on display cards, Hackensack, N.J.

SHIPPED: 10–26–62 and 11–30–62, from New York, N.Y., by Sulray, Inc.

LABEL IN PART: (Display card) "Watch Pimples Vanish at a touch of the tip! Heals! Hides! Acne– Pimples– Blackheads Covers Up Skin Blemishes Sul* Ray Blem-Stick * * * Contains 4 Medicated ingredients prescribed by Doctors," and (tube) "Sul*Ray Blem-Stick Directions: As an aid in relief of acne pimples * * * Contains: Allantoin, Sulphur, Hexachlorophene, Resorcinol. Sulray, Inc., Distr. Tuckahoe, N.Y. Net Wt. 5 Gm."

LIBELED: 3–14–63, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling, namely, the display card, contained false and misleading representations that the article was adequate and effective as a treatment for healing blackheads, skin blemishes, and pimples; and 502(f)—the labeling failed to bear (1) adequate directions for use for the conditions for which the article was offered, and (2) a warning statement that if undue skin irritation developed or increased, use of the article was to be discontinued and a physician consulted.

DISPOSITION: 12–23–64. Consent—destruction.

8535. Micro-Dynameter device. Suit for injunction.

COMPLAINT FILED: On or about 7–20–62, Dr. Walter F. Jones and Dr. Darlesqua R. Jones, Downingtown, Pa., and Dr. Walter P. Billstein, Chester, Pa., filed a complaint for injunction in the United States District Court for the District of Columbia against George P. Larrick, Commissioner of Food and Drug Administration, and Dr. Kenneth L. Milstead, Deputy Director, Bureau of Enforcement, Food and Drug Administration.

NATURE OF CHARGE: The complaint alleged that the plaintiffs, Dr. Walter Jones and Dr. Darlesqua Jones, were the owners of one *Micro-Dynameter device;* that the plaintiff, Dr. Walter Billstein, was also the owner of one *Micro-Dynameter device;* that such owners utilized the devices as an aid in diagnosis for the purpose of helping, in conjunction with the application of their knowledge as licensed chiropractors, in the determination of the existence of spinal nerve impingements and interference, and in the diagnosis of nerve pressures caused by subluxation of the vertebra; that the owners were under no legal duty to permit the defendants to have access to or copy records showing the movement in interstate commerce of the devices or the holding thereof during or after such movement; that the defendants had orally made requests upon the Joneses and threatened to make a similar request upon Billstein, and would make, unless enjoined, a request for information as aforesaid under threat of criminal prosecution of the plaintiffs and seizure of the devices; that the defendants had threatened to seize the devices from the plaintiffs by legal process; that the defendants had issued a press release, dated 6–21–62, wherein defendants had defamed users of the devices by declaring that they had "hoodwinked" thousands of patients; that the devices could not aid the licensed practitioner in the healing arts; that the United States Court of Appeals at Chicago (7th Circuit), by implication, had declared that the devices could not be safe for use under any claim even if limited to the single claim as an aid in diagnosis of nerve pressures caused by subluxation of the vertebra; and that reliable scientists and engineers would readily assert that the devices could be of beneficial aid to the practitioner of the healing arts for such purpose; and that, by reason of the acts of the defendants, immediate irreparable loss and damage would result to the plaintiffs.

PRAYER FOR RELIEF: That the defendants be preliminarily enjoined (1) from entering upon the premises of the plaintiffs and from requesting access to or copying records showing movement in interstate commerce, or the holding of the device known as *Micro-Dynameter,* (2) from seizing or attempting to seize the device from the plaintiff. (3) from issuing any statements or press releases reflecting upon the integrity of the plaintiffs, or in any way bringing the plaintiffs into disrepute because of their use of the device; and that, after final hearing, the defendants be permanently enjoined from performing any of such acts.

DISPOSITION: On 9–28–62, after submission by the defendants of a motion for dismissal of the complaint, and by the plaintiff of a motion for preliminary injunction, and after consideration of the record, the memoranda filed by the parties and the arguments of counsel, the court granted the defendants' motion, denied the plaintiffs' motion and dismissed the action with prejudice.

8536. Jacuzzi Whirlpool Bath. (F.D.C. No. 50599. S. No. 93–832 A.)

QUANTITY: 25 devices, at St. Louis, Mo., in possession of Bullard Distributing Co.

SHIPPED: On unknown dates within the last 5 years and between 9–10–64 and 10–13–64, from Berkeley, Calif., by Jacuzzi Research, Inc.

LABEL IN PART: (Metal plate on device) "Jacuzzi Whirlpool Bath * * * Model * * * Jacuzzi Research, Inc. Berkeley, Calif." and (shipping ctn.) "Model * * * No. * * * New Compact Portable Jacuzzi Whirlpool Bath * * * Manufactured by Jacuzzi Research, Inc. * * * Berkeley, California."

ACCOMPANYING LABELING: Undetermined numbers of booklets entitled "Jacuzzi Whirlpool Bath Instructions and General Information"; leaflets entitled "Jacuzzi's Jet Stream of Surging Warm Water" (reprint from advertisement in the Globe Democrat 12–8–63), "Great Pleasure Awaits You," and "Because of a Father's Love"; advertisement mats entitled "The Gift of Health" and "Gift of Health is the Greatest Gift of All."

RESULTS OF INVESTIGATION: The printed material which accompanied the article as labeling was prepared in part by the dealer.

Inspection of the photographs and the literature indicated the device was a submersible electric water pump with an attached tube for aerating the water before ejection from the pump.

LIBELED: 11–5–64, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective for the treatment of tensions, pains, miseries, chronic arthritis, bursitis, neuritis, rheumatism, backache, footache, nerves and poor circulation, and that use of the article would give the user year-round good health, condition the body, tone up the body, and keep the user in top physical condition; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for polio, arthritis, aching back, pneumonia, heart trouble, circulatory ailments, and to retard the aging process, which were the conditions and purposes for which the article was offered in oral statements made on 9–2–64, by Jim Koessel, salesman for Bullard Distributing Co.

DISPOSITION: On 2–23–65, Henry Bullard, president of Bullard Distributing Co., claimant, having consented to the entry of a decree without admitting the allegations of the libel, a decree of condemnation was entered and the article was ordered released under bond for relabeling. The decree also ordered that the claimant and his officers, agents, attorneys, employees, representatives and all other persons in active concert or participation with him be permanently enjoined from:

(1) Introducing into interstate commerce, any device designated as "*Jacuzzi Whirlpool Bath*" or the same device by any other designation or any similar device which

(a) is accompanied by leaflets entitled "Jacuzzi's Jetstream of Surging Warm Water"; leaflets entitled "Because of a Father's Love"; pamphlets entitled "Great Pleasure Awaits"; the booklets entitled "The Jacuzzi Whirlpool Bath"; the advertisement mat entitled "The Gift of Health"; or the advertisement mat entitled "Gift of Health is The Greatest Gift of All"; or by any other written, printed, or graphic matter which represents or suggests that the device is adequate and effective for the treatment of tensions, pains, miseries, chronic arthritis, bursitis, neuritis, rheumatism, backache, footache, nerves and poor circulation, and that the use of the article will give the user year-round good health, condition the body, tone up the body and keep the user in top physical condition or for any similar purpose, or

(b) does not bear or is not accompanied by labeling which states each and every purpose for which the device is intended or for which it is recommended, suggested, prescribed by advertisement or oral representations or any other means, together with sufficient information to enable the layman to use the device safely and effectively for each such purpose.

(2) Doing any act with respect to any of such devices, while held for sale after shipment in interstate commerce, which results in any such device

(a) being accompanied by any written, printed or graphic matter referred to in subparagraph (1) above;

(b) by failing to bear or be accompanied by labeling which states each and every purpose for which the device is intended, or for which it is recommended, suggested, prescribed by advertisement or oral representation or by any other means, together with sufficient information to enable the layman to use the device safely and effectively for each such purpose.

8537. Ultrasonic device, polysine generator device, and electronic heating device. (F.D.C. No. 51095. S. Nos. 22–964/6 B.)

QUANTITY: 1 *ultrasonic device*, 1 *polysine generator device*, and 1 *electronic heating device*, at Austin, Tex., in possession of George M. Willms, Jr.

SHIPPED: On unknown dates, from St. Louis, Mo., and Chicago, Ill.

RESULTS OF INVESTIGATION: Investigation indicated that the articles were prescription devices in the possession of a person not licensed by law to use or to order the use of the machines.

The *ultrasonic device* consisted of an electronic chassis, circuit and cover which was also the control panel. The control panel contained a wattmeter, timer, pilot light, intensity control, and storage well to hold the applicator. The electronic circuit produced 1000-kilocycle frequency which was applied to the transducer in the applicator head. The transducer converted electrical energy into ultrosonic energy which, when absorbed by the patient's tissue, produced deep heating of the tissue.

The *polysine generator device* consisted of an electrical instrument that produced a variety of wave shapes of varying frequencies which, through pad electrodes, were applied to the body. (Such currents have been applied generally in the medical field.) The device contained one direct current and one alternating current meter (graduated to milliamperes), two meter switches for high and low settings, one wave frequency scale, one current selector switch, one vernier control switch, one main control switch, one filter switch, one motor and one transmitter switch, and one pole changer switch, together with pad electrode attachments.

The *electronic heating device* consisted of an electronic instrument for production of 27.12-megacycle frequency of electrical current. This energy was applied to the body through two electrode pads. (This type of radiation has been used in physical therapy under the direction of a licensed practitioner.) The device contained one starter-switch button, one dosage timer, one intensity control, one power-output meter, and two heat pads for body application.

LIBELED: 3–4–65, W. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling of the devices failed to bear adequate directions for use and they were not exempt from such requirement.

DISPOSITION: 4–23–65. Default—delivered to the Food and Drug Administration.

8538. Detoxacolon device. (F.D.C. No. 50679. S. No. 112–175 A.)

QUANTITY: 1 device, at Fort Stockton, Tex., in possession of P. H. Cordero, D.C.

SHIPPED: On unknown date, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Inspection showed that the device consisted of a pressurized enema device intended for colonic irrigation, to which an oxygen tank had been attached. A wall-mounted metal control panel included connections for attachment to a hot- and cold-water supply, 2 inlet valves, an outlet valve, a temperature gauge for controlling the administration of hot and cold water, and a visual water-level gauge. Also included were other component parts such as flexible tubing, a metal pedestal, and a rectal applicator.

LIBELED: 10–22–64, W. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and it was not exempt from such requirement, since it was a prescription device within the meaning of regulations and it failed to comply with all of the conditions for exemption prescribed by regulations.

DISPOSITION: 12–8–64. Default—delivered to the Food and Drug Administration.

8539. Mathison Chevruel Pendulum device. (F.D.C. No. 50883. S. No. 105–662 A.)

QUANTITY: 29 individually bagged devices at Olympia, Wash.

SHIPPED: 12–10–63, from Los Angeles, Calif., by Volney G. Mathison.

ACCOMPANYING LABELING: Leaflet, enclosed in device's clear cellophane bag, entitled "The Mathison Chevruel Pendulum," and book entitled "The Secret Power of the Crystal Pendulum."

RESULTS OF INVESTIGATION: Copies of the above book and leaflet, including copies of the leaflet bearing the additional rubber-stamped statement "Do not use in lieu of medical diagnosis or treatment," had been shipped by the shipper for the purpose of promoting sales of the article.

Examination showed the article to consist of a solid, colorless, plastic sphere about 1 inch or 1¼ inch in diameter, attached to a gold-colored metal chain about 10 inches long. In use, the device was held free-swinging, by the chain, above a flat surface and the swinging of the ball was represented as being of hypnotic, diagnostic, and therapeutic significance.

LIBELED: 12–17–64, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for inducing a state of self-hypnosis during which the user could successfully treat and cure arthritis, all cases of serious physical ailments, induce health and well-being in the user, heal heart ailments, and improve other unnamed physical ailments; that the article was capable of diagnosing or predicting the sex of unborn children and diagnosing whether or not the user was pregnant within as little as one minute after the onset of pregnancy; that, through use of the article, the user could determine whether any dish of food would be beneficial to or disagree with the user and whether the food was stale,

spoiled, overcooked, undercooked, or contaminated, and whether or not poisons from sprays or chemicals were present in the food; that, through use of the article, the user could immediately observe the response of his subconscious mind to a conscious question, or command, or decision and be enabled to communicate with his subconscious mind in a self-strengthening manner; and that, if the pendulum failed to swing during use, this indicated that the conscious and subconscious mental processes of the user were in a state of serious disagreement; and 502(f)(1)—the labeling of the article failed to bear adequate directions for the intended uses of the article and it was impossible to prepare adequate directions for use, since the article was worthless for any diagnostic, therapeutic, or medical purpose.

DISPOSITION: 2–16–65. Default—delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

8540. Neomycin medications. (F.D.C. No. 51381. S. Nos. 30–608/9 B.)

QUANTITY: 1 case containing 47 ¼-lb. bags of *neomycin and vitamins medication*, and 2 cases, each containing 200 14.3-gm. bags of *neomycin sulfate medication*, at Statesville, N.C.

SHIPPED: Between 10–31–64 and 12–8–64, from Park Ridge, N.J., by Products Blending Co.

LABELS IN PART: (Bag) "Water Soluble Neomycin & Vitamins Each Packet Contains: Neomycin base (as sulfate) 20 gms. Vitamin A 1,000,000 units Vitamin E 250 units Will medicate 50 to 128 gallons poultry or livestock drinking water G. and M. Sales Company, Inc., Statesville, N.C." and (case) "Water Soluble Neomycin Sulfate and Vitamins * * * Neomycin is Effective for Enteritis–Scours–Chronic Respiratory Disease–Bluecomb–Diarrhea Dosage * * * For Veterinary Use Only * * * G. and M. Sales Company, Inc. Statesville, N.C."; (bag) "Neomycin Sulfate (10 gms. Neomycin Base) Water Soluble Antibiotic Will medicate 50 gallons poultry or livestock drinking water G. and M. Sales Co., Inc. Statesville, N.C." and (case) "Water Soluble Neomycin Sulfate * * * For use in drinking water of Chickens, Turkeys, Calves and Swine Neomycin is effective for Enteritis–Scours–Chronic Respiratory Disease–Bluecomb–Diarrhea Dosage: * * * G. and M. Sales Company, Inc. Statesville, N.C."

LIBELED: 5–14–65, W. Dist. N.C.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the articles were adequate and effective in the treatment of chronic respiratory disease; 502(b)(1)—the articles failed to bear a label containing the name of the manufacturer, packer, or distributor since their labelings bore the name "G. and M. Sales Company, Inc.," without a qualifying phrase, such as "Manufactured for and Packed by _____," "Distributed by _____," or other similar phrase, as provided by regulations; and 502(f)(1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 6–18–65. Default—destruction.

8541. Dimethyl sulfoxide and Dymasol. (F.D.C. No. 51017. S. No. 31–284 B.)

QUANTITY: 2 drums containing a total of 525 lbs. of *dimethyl sulfoxide*, and 321 1-pt. unlabeled and labeled btls. of *Dymasol*, at Hialeah, Fla., in possession of Zirin Laboratories International, Inc.

*See also No. 8520.

SHIPPED: (*Dimethyl sulfoxide*) 12–18–64, from Phillipsburg, N.J.

LABEL IN PART: (Drum) "490 Lb. Dimethylsulfoxide * * * Actual Anlysis of * * * Assay ((CH3) 250) 99.9% * * * For Laboratory Use Only," and (btl.) "Dymasol Contains: Dimethyl Sulfoxide 80% * * * For Veterinary Use Only For Experimental Use Only * * * Distributed by Zirin Laboratories Int'l., Inc. Miami 48, Florida."

ACCOMPANYING LABELING: Leaflets entitled "Newsletter," some being addressed to "Dear Doctor," concerning the article *dimethyl sulfoxide* (DMSO), and some addressed to "Horsemen" and some addressed to "Dealer," concerning the article *Dymasol.*

RESULTS OF INVESTIGATION: The article in the bottles was manufactured by Zirin Laboratories International, Inc., in part, from the bulk raw material in the drums. The accompanying labeling was printed on order of Zirin Laboratories International, Inc.

LIBELED: 2–12–65, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling of the articles in the drums and the bottles, namely, the bottle label and the printed material described above, accompanying the articles, contained statements which represented and suggested that the articles were limited by Federal law for animal and laboratory tests; that the articles were scientifically considered to be among the most important medical events of this century, comparable to the discoveries of penicillin, insulin, and other outstanding life-saving drugs, vaccines, and antibiotics; that the articles were adequate and effective as a treatment for second-degree burns, colds or sinusitis, dermatoses, fungus, and other infections in horses; and that the articles fight germs, which statements were false and misleading since they were contrary to fact and since the articles were not adequate and effective for such purposes; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes and conditions for which the articles were intended.

DISPOSITION: 3–16–65. Zirin Laboratories International, Inc., claimant, having consented to the entry of a decree, the court adjudged the article to be misbranded within the meaning of 502(f)(1), and entered a decree providing for condemnation of the article and its release to the claimant, under bond, to be brought into compliance with the law.

8542. **Veterinary drugs.** (F.D.C. No. 50834. S. Nos. 88–948/50 A.)

QUANTITY: 10 30-cc. vials, 12 30-cc. vials, 9 30-cc. vials, and 8 100-cc. vials, at Springfield, Ill.

SHIPPED: Between 6–3–64 and 8–10–64, from Oakland, Calif., by H. C. Burns Co., Inc.

LABEL IN PART: (Vials) "Sterile Solution Bo-Se * * * 2506517," "Sterile Solution E–Se * * * 1546414," and "Mu-Se * * * Multiple Dose Vial Product No. LP525–1 2666409."

ACCOMPANYING LABELING: Printed matter entitled "Control STD," "STD Questions & Answers," and "H.C. Burns Catalog"; copy of 8th Annual H.C. Burns Company Symposium "Selenium–Tocopheryl Deficiency Diseases"; leaflets entitled "Re: Anti-Inflammatory Action of our Selenium–Vitamin E Products," by "G.C.McC.," "Rehse Feedlot Trial Results," "Selenium-Tocopherol in Veterinary Practice, L. M. Koger, D.V.M." and "Outline on Selenium–Tocopherol, by Klaus Schwarz, M.D."; and letters dated April 20, 1964 from H.C.

Burns to Mr. Ralph A. Vierno and from Klaus Schwarz, M.D., to Dr. H. C. Burns.

LIBELED: 11–24–64, S. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment of disease conditions in 18 species of animals, including man; and for numerous disease conditions of most organs in the body; abortion; arthritis; joint ill in hogs; weight gain; for use in the treatment of swine, dogs, dairy cattle, small animals, chickens, turkeys, and goats; Brisket disease; organic phosphate poisoning; for intraperitoneal use; and inflammatory disorders; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes and conditions for which the articles were intended, and the articles were not exempt from such requirement, since they were veterinary prescription drugs which were new drugs subject to 505 and their labeling containing information for the use of such drugs was not, as required by regulations, substantially the same as the labeling authorized by the effective new-drug applications with respect to such drugs.

DISPOSITION: 3–1–65. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

8543. Prednisolone tablets. (F.D.C. No. 51111. S. Nos. 54–781/3 B.)

QUANTITY: 30 500-tablet btls., 97 100-tablet btls., and 262 100-tablet btls., at Baltimore, Md.

SHIPPED: Between 10–12–63 and 1–26–65, from New York, N.Y., by Davis-Edwards Pharmacal Corp.

LABEL IN PART: (Btl.) "Carroll Prednisolone 5 mg. Distr. by The Carroll Chemical Co. Baltimore, Md. * * * Caution: Federal law prohibits * * * For dosage and indications see package insert."

ACCOMPANYING LABELING: Package insert reading in part "Prednisolone Oral * * * March 28, 1962."

RESULTS OF INVESTIGATION: The article of drug was repacked by the dealer from bulk lots.

Analysis showed that the article contained from 68.8 percent to 74.8 percent of the declared amount of prednisolone. The limit allowed by the United States Pharmacopeia was 90 to 110 percent.

LIBELED: 3–8–65, Dist. Md.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as a drug, "*Prednisolone Tablets*," the name of which was recognized in an official compendium, the United States Pharmacopeia, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Prednisolone 5 mg." was false and misleading as applied to a product containing less than the declared amount of this ingredient.

DISPOSITION: 4–2–65. Default—destruction.

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*See also Nos. 8503, 8513, 8514, 8529, 8530.

8544. **Dextro-amphetamine sulfate capsules.** (F.D.C. No. 51077. S. No. 89–411 A.)

QUANTITY: 208 100-capsule btls. and 68 250-capsule btls., at Philadelphia, Pa., in possession of Jan Laboratories.

SHIPPED: Between 3–14–62 and 3–29–62, from Philadelphia, Pa., to Vienna, Va., by Jan Laboratories, and thereafter returned to Philadelphia, Pa.

LABEL IN PART: (Btl.) "Capsules * * * Dextro A.M. Caps 10 mgm. Gradual Release Capsules * * * Each A.M. Cap Contains: Dextro Amphetamine Sulfate 10 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 79 percent of the declared amount of dextro-amphetamine sulfate.

LIBELED: 2–12–65, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Dextro Amphetamine Sulfate 10 mg." was false and misleading as applied to a product containing less than the declared amount of this ingredient.

DISPOSITION: 3–17–65. Default—destruction.

8545. **Liver injection.** (F.D.C. No. 50948. S. No. 23–185 A.)

QUANTITY: 391 10-cc. vials, at Buffalo, N.Y., in possession of Direct Laboratories, Inc.

SHIPPED: 1–2–62, from Chicago, Ill.

LABEL IN PART: (Vial) "No. 2268 * * * Liver Injection N.F. 20 Micrograms each cc. contains: Vitamin B_{12} Activity 20 mcg.—Direct Laboratories, Inc. Buffalo, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 75 percent of the declared amount of viitamin B_{12}. The article was repacked by the dealer into vials described above.

LIBELED: 2–9–65, W. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, "Liver Injection N.F.," the name of which was recognized in an official compendium, the National Formulary, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "each cc. contains: Vitamin B_{12} Activity 20 mcg." was false and misleading.

DISPOSITION: 3–15–65. Default—destruction.

8546. **Rubber prophylactics.** (F.D.C. No. 50757. S. No. 100–059 A.)

QUANTITY: 80 ctns., each containing 12 12-unit pkgs., at San Francisco, Calif.

SHIPPED: 8–28–64, from New York, N.Y., by National Hygienic Products Corp.

LABEL IN PART: (Pkg.) "One Dozen Rubber Prophylactics—Convoys No. 54—Mfg. by Aronab Products Co., San Francisco, Calif."; (foil wrapper) "One Rubber Prophylactic Convoys—Mfg. by Aronab Products Co., San Francisco, Calif."

RESULTS OF INVESTIGATION: Examination showed that 3 percent of the 100 units examined were defective in that they contained holes.

LIBELED: 12–3–64, N. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(b)(1)—the article was in package form,

and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, since the article was not manufactured by Aronab Products Co., San Francisco, Calif.

DISPOSITION: 1–25–65. Default—destruction.

8547. **Rubber prophylactics.** (F.D.C. No. 50686. S. No. 27–250 A.)

QUANTITY: 39 1-gross ctns. at Chicago, Ill.

SHIPPED: 5–18–64, from New York, N.Y., by Goodwear Rubber Co., Inc.

LABEL IN PART: (Ctn.) "One Gross 3'S Rolled Prophylactics Koin-Pack Plastic Containers Manufactured by L. E. Shunk Latex Products Div. of The Akwell Corp., Akron, Ohio," (plastic container) "Mfg. by L. E. Shunk Latex Products Co. Akron, O. Koin-Pack One Latex Prophylactic."

RESULTS OF INVESTIGATION: Examination of 223 prophylactics showed that 0.9 percent contained holes.

LIBELED: 10–26–64, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statements (carton) "Assists in protecting health through the prevention of venereal diseases and the re-infection of the female with trichomonas," and (plastic container) "Sold for the prevention of disease," were false and misleading as applied to a product containing holes.

DISPOSITION: 1–12–65. Default—destruction.

8548. **Rubber prophylactics.** (F.D.C. No. 50337. S. No. 41–783 A.)

QUANTITY: 15 gross ctns. and 108 2-unit pkgs., at Dallas, Tex.

SHIPPED: 6–16–64, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Coronet * * * Manufactured for M & M Rubber Co. Kansas City 41, Missouri * * * Sold Only For The Prevention of Disease."

RESULTS OF INVESTIGATION: Examination showed that 8 percent of the units tested were defective in that they contained holes.

LIBELED: 8–27–64, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold Only For The Prevention of Disease" was false and misleading.

DISPOSITION: 10–29–64. Default—destruction.

DRUGS FOR VETERINARY USE

8549. **Medicated poultry feed.** (F.D.C. No. 51134. S. Nos. 6–321/2 B.)

QUANTITY: 15 100-lb. bags and 40 100-lb. bags, at Dubuque, Iowa, in possession of Hendricks Feed Co.

SHIPPED: The furazolidone ingredient of the article was shipped on 9–28–64, from Wauseon, Ohio.

LABEL IN PART: (Tag on bag (15-bag lot)) "Hendricks Best 34% poultry concentrate medicated * * * Active drug ingredient: Furazolidone .011% * * * Manufactured by Hendricks Feed Company, Dubuque, Iowa," and (40-bag lot) "Hendricks Best 26% concentrate medicated * * * Active drug ingredient: Furazolidone .00825% * * * Manufactured by Hendricks Feed Company, Dubuque, Iowa."

RESULTS OF INVESTIGATION: Analysis showed that the articles contained (15-bag lot) approximately 25.5 percent and (40-bag lot) approximately 31.3 percent of declared amount of furazolidone. The articles were manufactured by the Hendricks Feed Co., in part, from a drug ingredient containing 0.55 percent furazolidone.

LIBELED: 2–24–65, N. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the articles differed from that which they purported to possess; and 502(a)—the label statements "Furazolidone .011%" and "Furazolidone .00825%" were false and misleading as applied to products containing less than the declared amounts of this ingredient.

DISPOSITION: 3–31–65. Default—delivered to a charitable institution for use as poultry feed.

8550. Profalac feed mix (2 seizure actions). (F.D.C. Nos. 51018/19. S. Nos. 95–442 A; 617 A.)

QUANTITY: 34 50-lb. bags at Rogers, Ark.; and 17 50-lb. bags at Griffin, Ga.

SHIPPED: On 5–27–64 and 9–15–64, from Caldwell, Ohio, by Bingman Laboratories, Inc.

LABEL IN PART: (Bag) "Bingman's Profalac Feed Mix * * * Active ingredient: Phthalylsulfacetamide—160 gm. per lb.—35% * * * Bingman Laboratories, Inc., Caldwell, Ohio."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 60 percent of the declared amount of phthalylsulfacetamide.

LIBELED: 2–5–65, W. Dist. Ark.; and 2–11–65, N. Dist. Ga.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Phthalylsulfacetamide 160 gm. per lb." was false and misleading as applied to a product containing less than the declared amount of this ingredient; and 502(a)—the bag label contained false and misleading representations that the article was adequate and effective to control outbreaks of coccidiosis in chickens and turkeys; as an aid in the prevention of coccidiosis; to help prevent laying slumps in poultry; to maintain feed consumption; for reducing mortality in poultry and swine; and that it was useful in combatting *Pasteurella aviseptica* and *Salmonella pullorum*.

DISPOSITION: 2–17–65 and 4–20–65. Consent—claimed by Bingman Laboratories, Inc., reconditioned and repackaged.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

8551. Regimen tablets. (F.D.C. No. 49755. S. No. 6–505 A.)

QUANTITY: 19 78-tablet boxes and 21 156-tablet boxes, at Washington, D.C.

SHIPPED: 4-12-63, from Long Island City, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen–Tablets * * * contain: (In Green tablets) Vitamin D (irradiated yeast), B_1, B_2, B_6, and C, Niacinamide, Calcium Pantothenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride,

*See also Nos. 8502–8504, 8513, 8514, 8522, 8526, 8527, 8529, 8534, 8536, 8539–8545, 8547–8550.

Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Ammonium Chloride * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular in boxes reading in part "Reduce with the Regimen Plan."

LIBELED: 1-30-64, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen plan" could do most everything medical science could do to help you attain your goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were more susceptible to cancer.

DISPOSITION: 2-28-64. Default—destruction.

8552. Cold-Tac capsules. (F.D.C. No. 49980. S. No. 61-861 A.)

QUANTITY: 15¾ cases, each containing 24 12-capsule pkgs., and 10 cases, each containing 12 24-capsule pkgs., each pkg. being enclosed in a cardboard sleeve, at Huntington Park, Calif.

SHIPPED: Between 12-11-63 and 1-22-64, from Buffalo, N.Y., by Vitamin Capsule Corp.

LABEL IN PART: (Sleeve) "Cold-Tac Timed Disintegration Capsules Dosage: Adults 1 capsule in the morning and 1 capsule at bed time. Distributed by Daylin Drugs, Inc. Huntington Park, Calif. Continuous Relief of Nasal Congestion Due to Colds and Hay Fever * * * Each Capsule Contains Belladonna Alkaloids 0.16 Mgm. Atropine Sulfate 0.024 Mgm. Scopalamine Hydrobromide 0.014 Mgm. Hyoscyamine Sulfate 0.122 Mgm. Phenylpropanolamine Hydrochloride 50.0 Mgm. Chlorpheniramine Maleate 1.0 Mgm. Pheniramine Maleate 12.5 Mgm."

LIBELED: 4-17-64, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that a single *Cold-Tac capsule* containing the amounts of ingredients declared in the label would provide 12 hours of continuous relief of excessive nasal discharge, running nose, watering of the eyes, swelling of the nasal tissues, and stuffy, congested feeling caused by the common cold and hay fever.

DISPOSITION: 3-2-65. Default—destruction.

8553. Caltac capsules. (F.D.C. No. 49481. S. No. 30-128 X.)

QUANTITY: 67 24-capsule boxes and 105 12-capsule boxes; and 3 cases, each containing 6 doz. 24-capsule boxes, and 3 cases, each containing 12 doz. 12-capsule boxes, at Los Angeles, Calif.

SHIPPED: 7-12-63, from Buffalo, N.Y., by Vitamin Capsule Corp.

LABEL IN PART: (Box) "Gives up to 12 hours relief with one Capsule * * * Caltac Timed Disintegration Capsules * * * Distributed by Medco Pharmacies, Inc. Los Angeles, California Continuous Relief of Nasal Congestion Due to Colds Allergies and Hay Fever Warning * * * Each Capsule Contains: Belladonna Alkaloidal Salts, Total 0.16 mgm. Atropine Sulfate 0.024 mgm. Hyoscyamine Sulfate 0.122 mgm. Scopolamine Hydrobromide 0.014 mgm.

Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. * * * two capsules, taken separately at 12 hour intervals, bring you continuous day and night relief from nasal congestion, watery eyes, excessive sneezing, and running nose, due to common colds and hay-fever."

LIBELED: 10–23–63, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the box label contained statements which represented and suggested that a single capsule containing only "Belladonna Alkaloidal Salts, Total 0.16 mgm.; Phenylpropanolamine Hydrochloride 50 mgm.; Chlorpeniramine Maleate 1 mgm.; and Pheniramine Maleate 12.5 mgm.," would provide 12 hours of continuous relief of nasal congestion, watery eyes, excessive sneezing, and running nose due to colds, allergies and hay fever, which statements were false and misleading, since the article was not adequate and effective for such purposes when taken as directed in the labeling.

DISPOSITION: On 4–3–64, pursuant to stipulation by the Government and the claimant, Vitamin Capsule Corp., the court ordered that the libel action be transferred to the Eastern District of Michigan. On 7–22–64, the claimant filed an answer denying that the article was misbranded; on 10–30–64, interrogatories were served upon the claimant; and on 5–18–65, the claimant was adjudged in default for failure to answer the interrogatories and a decree of condemnation and destruction was entered.

8554. Vaginettes vaginal tablets. (F.D.C. No. 50284. S. No. 80–040 A.)

QUANTITY: 16 unlabeled ctns., each containing 6,000 tablets in strips of 3 tablets each, at New York, N.Y., in possession of Vaginettes, Inc.

SHIPPED: On unknown date, from Baltimore, Md.

LABEL IN PART: (Insert label) "Vaginettes Professional Vaginal Tablets Manufactured under U.S. Gov't Patent—1962 Each tablet contains Quinol, Tartaric Acid, Boric Acid, Sodium Bicarbonate and excipients Sodium Lauryl Sulfate Contents: 12 – 1.15 Gram Tablets Directions * * * Dist. by Vaginettes, Inc. 25 Central Park West, New York City."

ACCOMPANYING LABELING: Package inserts reading in part "Personal Order Form Dorothy Dawson Vaginette Suite 9I 25 Central Park West"; leaflets entitled "Vaginetts Fight Vaginal Problems New Way Without Douching," "Vaginette Vaginal Tablets The NEW medical discovery for perfect daily vaginal hygiene," and "Vaginette Vaginal Tablets Now you can throw away your douche bag . . ."

RESULTS OF INVESTIGATION: The tablets of the article were manufactured in Baltimore, Md., prior to 4–6–64, and transported to South Hackensack, N.J., where the tablets were packed in strips and then transported to New York. In the normal course of the dealer's business operations the tablets were to be repacked into plastic boxes containing 12, 24, or 60 tablets.

LIBELED: On or about 6–19–64, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling, namely, the leaflets accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for overcoming vaginal itch, simple vaginitis, common vaginal discharges, and other infections; that use of the article stopped odors, killed germs, fought itch and discharge all day and all night long, and substituted for douching; and that the article could be used as often as desired.

DISPOSITION: 11–9–64. Consent—destruction.

8555. Soberettes. (F.D.C. No. 49806. S. Nos. 96–785/6 A.)

QUANTITY: 25 boxes, each containing 40 packets, and 98 boxes, each containing 40 packets, at Oakland, Calif.

SHIPPED: 12–16–63 and 12–20–63, from San Antonio, Tex., by Universal Pharmaceutical Co.

LABEL IN PART: (Packet) "Each capsule contains * * * 'Soberettes' Dosage: * * * % MDR * * * Keep out of reach of children: Distributed by: Universal Pharmaceutical Co. 827 W. Hildebrand San Antonio, Tex.," and (box) "Soberettes for overindulgence in food and drink."

LIBELED: 2–18–64, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the name of the article, "*Soberettes*," and a statement on the box label, contained false and misleading representations that the article was adequate and effective to make an intoxicated person sober.

DISPOSITION: The Universal Pharmaceutical Co. appeared as claimant and thereafter, on 8–17–64, pursuant to stipulation by the Government and the claimant, the case was transferred to the S. Dist. Texas. Interrogatories were served upon the claimant on 12–21–64. On 1–25–65, with the consent of the claimant, the court ordered that the article be forfeited and destroyed.

8556. Pollen-Ex filter device. (F.D.C. No. 43885. S. No. 69–092 P.)

QUANTITY: 16 individually ctnd. devices at Des Moines, Iowa.

SHIPPED: 7–22–59, from Chicago, Ill., by Associated Mills, Inc.

LABEL IN PART: "Pure-Air '99' Pollen-Ex Associated Mills Inc. Chicago, Illinois."

ACCOMPANYING LABELING: Circular reading in part "99.99 Pure with the Pollen-Ex Pure-Air 99 Electronic Filter"; card in carton entitled "Operating Instructions"; placard reading in part "Hay Fever, Asthma, Allergy, Sinus, Cold Suffers! Wonderful Relief – Pollen-Ex Pure Air 99 Amazing New Electronic Miracle"; and an advertising sheet reading in part "Banishes Pollen Dust Dirt Smoke . . . Pollen-Ex Pure-Air '99'."

RESULTS OF INVESTIGATION: Examination indicated that the article was a portable, box-shaped cabinet enclosing an electric fan, an ultraviolet lamp, and a filter pad or screen. In operation, the fan was intended to draw room air into the cabinet, to filter the air, to expose the air to ultraviolet rays emitted by a lamp, and to expel the air from the cabinet into the room.

LIBELED: 11–9–59, S. Dist. Iowa; libel amended 12–5–62.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving asthma, hay fever, and sinus conditions, and preventing colds and other respiratory and airborne infections; that the article released health-giving, invigorating negative ions; and that the "Permasterile" filter provided permanent germicidal action.

DISPOSITION: On 3–23–60, Associated Mills, Inc., claimed the devices; denied that the devices were misbranded; stated that the circulars were mailed separately and apart from the devices; and asked that the proceedings be dismissed. On 6–30–60, pursuant to stipulation by the parties, the case was transferred to the Southern District of Illinois, Northern Division, at Rock Island, Ill. On or about 8–1–60, pursuant to stipulation, the case was transferred to the Northern District of Illinois.

On 7–7–61, the Government served interrogatories upon the claimant. On 8–20–62, the claimant served some answers and some objections to the Government's interrogatories.

On 12–5–62, upon motion of the Government, the libel was amended to add the placards to the other pieces of labeling which had been libeled, and to charge that the article was misbranded while held for sale. Thereafter, the claimant moved to dismiss the amended libel and for a more definite statement, which motions were denied by the court on 3–29–63. On that date, the court also sustained in part and overruled in part the claimant's objections to the Government's interrogatories.

On 7–29–63, the claimant filed an answer to the amended libel. On 8–28–63, the claimant served interrogatories upon the Government.

Thereafter, the Government answered in part and objected in part to the claimant's interrogatories. On 1–6–64, the Government's objections were sustained in part and overruled in part.

On 12–28–64, upon agreement of the parties, the claim and answer of Associated Mills, Inc., was withdrawn and a default decree was entered which provided for the delivery of the articles to the Food and Drug Administration.

8557. Chin massager and facial patter devices. (F.D.C. No. 49971. S. Nos. 55–521/2 A.)

QUANTITY: 19 individually ctnd. *chin massager devices* and 10 individually ctnd. *facial patter devices*, at Kansas City, Mo.

SHIPPED: *Chin massager device*, between 12–2–63 and 4–8–64, from Anaheim, Calif., by Veltron Products, Inc.; *facial patter device*, on 5–30–63 and 4–8–64, from Anaheim, Calif., by S. L. McNair Corp.

LABEL IN PART: (Ctns.) "Veltron * * * Electronic Chin Massager [or "Facial Patter"] * * * A Product of The S. L. McNair Corporation, Anaheim, California."

ACCOMPANYING LABELING: Leaflet tied to *chin massager device* entitled "Veltron * * * Electronic Underchin Massager," and leaflet tied to *facial patter device* entitled "Veltron * * * Electronic Facial Patter."

RESULTS OF INVESTIGATION: Examination showed that the article, *chin massager*, consisted of a curved surface padded with plastic foam, with cylinder-shaped handle which served as housing for a vibrator motor, and included was a rubber strap which would go over the top of the head to secure the vibrator under the chin; and that the article, *facial patter*, consisted of a flat, white plastic paddle, 5 inches long by 1⅜ inches wide, the base of which served as a handle and housing for a vibrator motor.

LIBELED: 4–10–64, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling, namely, the leaflet entitled "Veltron * * * Electronic Underchin Massager" which accompanied the *chin massager device*, contained false and misleading representations that the article was adequate and effective for avoiding or correcting unsightly underchin and throat muscles, and sagging, flabby, underchin and throat wrinkles, and that treatment with the device was like having 1,800 magic fingers massaging your throat at one time; and 502(a)—the labeling, namely, the leaflet entitled "Veltron * * * Electronic Facial Patter" which accompanied the *facial patter device*, contained false and misleading representations that the article was adequate and effective to stimulate circulation, break down the buildup of fatty tissue, correct sagging muscles, firm the skin tissue, avoid or correct un-

sightly facial wrinkles, crow's feet, and bagginess under the eyes, and wrinkles on the brow and forehead.

DISPOSITION: 9–25–64. Consent—claimed by Songrand Corp., Kansas City, Mo., and released for relabeling. The devices were subsequently destroyed by the claimant.

8558. Electrical manicurist. (F.D.C. No. 50567. S. No. 25–461 A.)

QUANTITY: 20 ctns., each containing 1 device, at Chicago, Ill.

SHIPPED: 6–24–64, from Cleveland, Ohio, by Abar Manufacturing Co.

LABEL IN PART: (Ctn.) "Abar Manufacturing Co. * * * Cleveland 4 Ohio * * * Spruce Electrical Manicurist."

ACCOMPANYING LABELING: Leaflets entitled "Beauty At Your Fingertips"; and the following items of promotional literature entitled "For Personal Appearance," "Healthier Nails," "Price List Dated June 1, 1963," "Guarantee Registration Request," "The Spruce Tweezer," "Spruce Electrical Manicurist," "Please Note: The attachment key," "Important Caution," and "If this manicurist should ever need repairs."

RESULTS OF INVESTIGATION: Inspection indicated the device consisted of an induction-type electric motor housed in a small circular plastic case. A detachable cable led from the motor and terminated in a handpiece to which various accompanying manicuring tools could be attached as needed, such as nail shaper, shaper disc, buffer, buffer pad, callus eraser, cuticle lifter, cuticle brush, and others. When not in use, these small tools were stored in apertures provided in a shelf around the base of the case.

LIBELED: 9–14–64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that use of the device was a corrective treatment which would cure children and adults of the habit of biting fingernails; rejuvenate tissue; promote healthy nails; prevent hangnails, peeling of nails, and brittle nails; promote blood circulation in the fingers and stimulate nail growth; and promote growth of fingernails by stimulating the blood flow to the nails, thus assuring brisk circulation at the finger tips and faster growing, stronger, pliable, healthy nails and healthy hands.

DISPOSITION: 10–26–64. Consent—claimed by Abar Manufacturing Co. for relabeling.

8559. Beauty massager. (F.D.C. No. 50662. S. No. 83–030 A.)

QUANTITY: 272 individually ctnd. devices, at Neptune, N.J., in possession of N. K. Morris Manufacturing Co.

SHIPPED: 3–27–64, from Miami, Fla.

LABEL IN PART: (Ctn.) "Ling Yet Amazing Oriental Beauty Massager 9 Free Rolling Circulators * * * Massager Orientale—a magic-like beauty device * * * Distributed by N. K. Morris Mfg. Co. Neptune, N.J."

RESULTS OF INVESTIGATION: The devices, after shipment as described above, were repacked by the N. K. Morris Manufacturing Co., into the individual cartons.

Examination showed that the article consisted of a plastic oval-shaped device, slightly larger than the hand, one side of which contained 9 natural-colored, movable wood balls. In use, the ball side of the device was rubbed over the portions of the body being treated.

LIBELED: 10–13–64, Dist. N.J.

CHARGE: 502(a)—while held for sale, the carton label contained false and misleading representations that the article was adequate and effective to relieve painful headache in minutes, keep the skin young and firm, keep the muscles supple, firm sagging tissue, remove fatty tissue, trim off inches, and bring health to the user.

DISPOSITION: 12–1–64. Default—destruction.

8560. Acu-Finder devices, silver needles, and gold needles. (F.D.C. No. 49655. S. No. 54–252 X.)

QUANTITY: 5 *Acu-Finder devices*, 40 unlabeled *silver needles* and 24 unlabeled *gold needles*, at Bala-Cynwyd, Pa.

SHIPPED: Between 10–26–63 and 11–2–63 (the devices), and on unknown dates (the needles), from England.

LABEL IN PART: (Metal plate on front of device) "The Berkeley Acu-Finder"; (metal plate on back of device) "Manufactured by Berkeley Laboratories, Ltd., Oxford St., London."

ACCOMPANYING LABELING: Booklet entitled "Acupuncture"; pamphlet entitled "Berkeley Acupuncture"; and newsletter entitled "Acupuncture News, Volume 1, No. 25."

RESULTS OF INVESTIGATION: The accompanying labeling had been printed in England on order of Berkeley Acupuncture, Inc., Bala-Cynwyd, Pa.

Examination indicated that the device was an electrical circuit enclosed in a housing containing controls, a meter, and attached electrodes. The device was used to measure changes in the skin resistance on the body to determine the points of puncture by the needles in the treatment of disease.

LIBELED: 12–27–63, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the device was adequate and effective in the treatment of rheumatism, rheumatoid arthritis, osteoarthritis, migraine, sinusitis, asthma, insomnia, sciatica, skin disorders, fibrositis, lumbago, neuralgia, rhinitis, facial paralysis, hay fever, menstrual disorders, and nervous disorders.

DISPOSITION: On 6–23–64, Berkeley Acupuncture, Inc., filed a claim to the articles. On 7–1–64, upon consent of the claimant, the articles were ordered condemned and were ordered to be released under bond to claimant for export to the original supplier, Berkeley Laboratories, Ltd., London, England. On 1–27–65, claimant having failed to file a bond, or otherwise proceed, and the time for doing so having expired, the court ordered, upon motion of the Government, that the devices and a representative number of pieces of the promotional material be delivered to the Food and Drug Administration and that the balance of the promotional material be destroyed.

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1](8553, 8556) Seizure contested.
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[1] (8553, 8556) Seizure contested.

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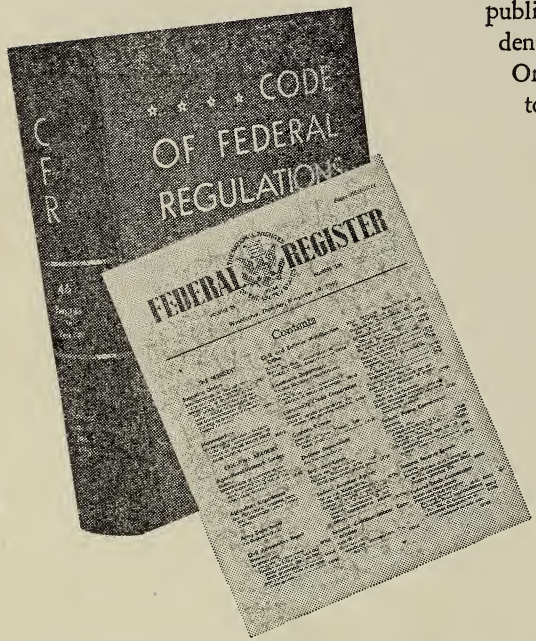

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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8561–8620

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial by the court, including, in one case, the return of some of the articles and the entry of a consent decree of permanent injunction, and, in one case, the granting of a motion for judgment on the pleadings; and in which, in one case, the action was dismissed upon the segregation and destruction of some of the articles; (2) criminal proceedings terminated, in one case, upon a plea of guilty and, in one case, upon a verdict of acquittal as to the individuals and of guilty as to the corporation; and (3) injunction proceedings in which decrees of permanent injunction were entered. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction procedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *December 27, 1966.*

CONTENTS*

*For omission of, or unsatisfactory ingredients statements, see No. 8570; failure to bear a label containing an accurate statement of the quantity of the contents, No. 8570; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 8570, 8586, 8615; cosmetic actionable under the drug provisions of the Act, No. 8617.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 8561–8620

Adulteration, Section 501(a)(1), the article consisted in whole or in part of a filthy substance; Section 501(a)(2)(A), the article had been held under insanitary conditions whereby it may have been rendered injurious to health; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from or its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e)(1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article purported to be and was represented as a drug composed, in part, of an antibiotic drug and (1) was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507, or (2) such certificate or release was not in effect with respect to such drug; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an approval of an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

8561. Various dipyrone solutions. (F.D.C. No. 51926. S. Nos. 37–993/8 B.)

QUANTITY: 6 individually ctnd. 30-cc. vials of *Viperone Solution* (for injection); 472 individually ctnd. 30-cc. btls. and 124 individually ctnd. 15-cc. btls. of *Viperone Solution* (for oral use); and 42 individually ctnd. 30-cc. vials and 223 individually ctnd. 5-cc. vials of *Salzoline injection*, at Hato Rey, P.R.

SHIPPED: Between 6–24–64 and 8–17–65, from Philadelphia, Pa., by Vitamix Pharmaceuticals, Inc.

LABELS IN PART: (Vial and ctn.) "Viperone Sol. 50% (Aminopyrinesulfonate Sodium) * * * Each 2 cc. contains: Dipyrone * * * 1 Gm. * * * Manufactured for Dorasol Laboratories Hato Rey, P.R."; (btl. and ctn.) "Viperone 50% Solution (Brand of Sodium Methylaminophenyldimethyl pyrazolone methanesulfonate) * * * for oral use only * * * Each cc. contains: Dipyrone * * * 0.5 Gm. * * * Vitamix Pharmaceuticals Incorporated Philadelphia, Pennsylvania"; and (vial and ctn.) "Salzoline Injection Each cc. contains: Dipyrone 500 mg. * * * Vitamix Pharmaceuticals Incorporated Philadelphia, Penna."

ACCOMPANYING LABELING: Inserts reading in part "Viperone 50% Solution Dipyrone" and "Viperone."

LIBELED: 12–8–65, Dist. P.R.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement, since the articles were prescription drugs and their labeling failed to bear, as required by regulations, adequate information for their use, including effects and any relevant hazards, contraindications, side effects, and precautions under which practitioners can use the drugs safely and for the purposes for which they were intended, including all the purposes for which they were advertised and represented in their labeling; 502(j)—the articles were dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in their labeling; and 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drugs.

DISPOSITION: 3–2–66. Default—destruction.

8562. Kennedy's Mixture. (F.D.C. No. 50964. S. Nos. 137–015/18 A.)

QUANTITY: 22 8-oz. individually ctnd. btls. of *Kennedy's Mixture with Laxative*, 82 8-oz. individually ctnd. btls. of *Kennedy's Mixture*, 70 80-tablet btls. of *Kennedy's Mixture Tablets with Laxative*, and 70 80-tablet btls. of *Kennedy's Mixture Tablets*, at Charlotte, N.C.

SHIPPED: 10–30–64, from York, S.C., by York Drug Co., Inc.

LABEL IN PART: (Btl. and ctn.) "Kennedy's Mixture with Laxative Active Ingredients: Sodium Citrate, Bismuth Subnitrate and Phenolphthalein [or "Kennedy's Mixture Active Ingredients: Sodium Citrate, Bismuth Subnitrate"] An Aid in Relief of Discomfort of Gas on the Stomach, Sour or Excess Acid Stomach, Flatulence, Heartburn due to Excess Acidity of the Stomach * * * Dose: Shake well and take one to two teaspoonfuls after meals in ¼ glass of water * * * Sole Distributor York Drug Co. York South Carolina," and (btl.) "Kennedy's Mixture Tablets with Laxative Active Ingredients Sodium Citrate, Bismuth Subnitrate and Phenolphthalein [or "Kennedy's Mixture Tablets Active Ingredients: Sodium Citrate and Bismuth Subnitrate"] * * * An Aid in Relief of discomfort of Gas on the Stomach, Sour or Excess Acid Stomach, Flatulence, heartburn Due To Excess Acidity of the Stomach Dose: Two Tablets after meals with water * * * Sole Distributor York Drug Company, Inc. York, South Carolina."

LIBELED: 1–4–65, W. Dist. N.C.

CHARGE: 502(a)—when shipped, the dosage instructions in the labeling of the articles, namely, the bottle and carton labels, considered in the setting which presented, suggested and implied that the articles were suitable for regular use by the laity over an indefinite period of time, in the treatment of gas on the stomach, sour and excess acid stomach, flatulence, heartburn due to excess acidity of the stomach, sore, burning, irritated stomach pains, and stomach in flame, which suggestion and implication were false and misleading in that the articles were not suitable for regular use by the laity over an indefinite period of time in the treatment of the aforesaid conditions, since said conditions were symptoms of ulcers and other chronic ailments which were not amenable to diagnosis or treatment by the laity; and 502(f)(1)—the labeling failed to bear adequate directions for use in conditions such as duodenal and stomach ulcers, which were suggested and implied by statements in newspaper and radio advertisements of the article, namely, (newspaper) "quick, effective relief from sore, burning, irritated stomach pains" and (radio) "Kennedy's Mixture for stomach pains, Soothes your Stomach when its in flame," and adequate directions for the lay user could not be written for such conditions.

502(a)—the bottle and carton labels of the *Kennedy's Mixture with Laxative* and *Kennedy's Mixture Tablets with Laxative* were misleading in that the label statements "An Aid in Relief of discomforts of Gas on the Stomach, Sour or Excess Acid Stomach, Flatulence, Heartburn due to Excess Acidity of the Stomach" and "Warning—Do not use when abdominal pain, nausea, or vomiting are present" were ambiguous and inconsistent with each other; and 502(j)—the *Kennedy's Mixture with Laxative* and *Kennedy's Mixture Tablets with Laxative* were dangerous to health, by virtue of their phenolphthalein content, when used with the frequency and duration suggested by the dosage instructions in their labeling.

DISPOSITION: 1–29–65. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE*

8563. Various prescription drugs. (Inj. No. 460.)

COMPLAINT FOR INJUNCTION FILED: 6–24–63, S. Dist. N.Y., against Bronx Drug Co., Inc., Bronx, N.Y., and Isaac Zonana, president.

ALLEGED METHODS OF OPERATION: The defendants were engaged in the business of repacking and relabeling various prescription drugs, and distributing and selling the drugs to retail pharmacies, mail-order drug houses, and other persons in the State of New York and elsewhere.

In conducting the repacking and relabeling operations of the business, the defendants employed the following methods:

(a) The defendants obtained from representatives of drug manufacturers, and other drug handlers, various prescription drugs which had been manufactured within and outside the State of New York, and were contained in packages bearing and containing the labeling of the original manufacturers;

(b) Among the prescription drugs obtained by the defendants were (1) drugs whose labels bore expiration dates that had expired, (2) antibiotic drugs which were from batches with respect to which certificates or releases issued pursuant to section 507 were in effect so long as such antibiotic drugs were not repacked or the expiration dates of such drugs had not expired, (3) new drugs,

*See also No. 8561.

for which approvals of new-drug applications filed pursuant to law were effective so long as such new drugs were not repacked or the expiration dates of such drugs had not expired, and (4) new drugs for which approvals of new-drug applications filed pursuant to law were not effective;

(c) The prescription drugs, when obtained by the defendants, were placed in stock where they remained until removed for the purpose of repacking;

(d) The prescription drugs, other than those whose expiration dates had expired, were repacked by placing the drug contents of large containers into smaller size dispensing containers and the drug contents of a number of small size containers into dispensing containers of a larger size;

(e) The containers of the repacked prescription drugs were labeled with photo-reproductions of the original manufacturer's labels to which had been added the name and address of either the corporation or individual defendant as a distributor of the drugs;

(f) Labeling, consisting of package inserts and bearing information for use of the repacked prescription drugs, as set forth in regulations, was placed in some containers of repacked drugs and omitted from other containers of repacked drugs; and

(g) Repacking and distribution operations were conducted without maintaining adequate records, including records of control numbers so that the complete manufacturing (including repacking) history of the repacked prescription drugs could be determined.

ALLEGED VIOLATIONS: The complaint alleged that the defendants introduced and caused to be introduced and delivered and caused to be delivered for introduction into interstate commerce, repacked new drugs which were in violation of 505(a) as described below; and that the defendants caused prescription drugs, other than those whose expiration dates had expired, to be repacked while held for sale after shipment in interstate commerce, which act resulted in the repacked drugs being misbranded.

CHARGE: Drugs bearing expired expiration dates, 502(a)—the labeling of the articles was misleading as applied to the articles which were not suitable for use after their expiration dates had expired; and 502(f)(1)—their labeling failed to bear adequate directions for use after their expiration date.

Repacked prescription drugs, 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement since their labels failed to bear identifying lot or control numbers from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations.

A number of the repacked prescription drugs, 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement, as provided by regulations, since the packages containing them were the packages from which they were to be dispensed and the labeling on or within the packages did not bear adequate information for the use of the drugs as prescribed by regulations.

A number of repacked new drugs, 505(a)—the articles were new drugs which may not be introduced and delivered for introduction into interstate commerce, since no approvals of new-drug applications filed pursuant to law were effective with respect to such articles.

A number of repacked new drugs, 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and the articles were not exempt from such requirement, as provided by regulations, since the packages containing the articles were the packages from which the articles were to be dispensed and

the labeling on or within the packages, bearing the information for the use of the articles, was not the labeling authorized by the new-drug applications which were effective with respect to such articles prior to their repacking.

DISPOSITION: On 6–24–63, the court issued a temporary restraining order enjoining the defendants from continuing the violations alleged in the complaint. On 7–16–63, the court heard argument by the parties on the Government's motion for a preliminary injunction and, on 7–29–63, it granted such motion; the preliminary injunction was entered on 8–8–63. Thereafter, the defendants served written interrogatories upon the Government which were subsequently answered. The Government then filed requests for admissions which were answered by the defendants. On 11–10–64, the defendants having consented to the entry of a permanent injunction without admitting the violation of any statute, the court entered a decree permanently enjoining and restraining the defendants from doing any of the following acts:

(a) introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce repacked drugs which may only be dispensed upon prescription pursuant to 21 U.S.C. § 353(b) unless said drugs comply with all of the conditions of the exemption regulations, 21 C.F.R. 1.106(b), [annexed] including those conditions which require:

(i) that the label of a prescription drug shall bear an identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

(ii) that the labeling on or within the package from which the prescription drug is to be dispensed shall comply with the requirements of regulation 21 C.F.R. 1.106(b)(3);

(b) introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce repacked drugs composed wholly or partly of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless there are certificates or releases issued pursuant to 21 U.S.C. 357 in effect for said repacked drugs in their repacked condition;

(c) introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce any drug repackaged by defendants, which is a New Drug within the meaning of 21 U.S.C. 321(p), unless approval of a new drug application or supplemental new drug application filed pursuant to 21 U.S.C. 355(b) is effective with respect to such repackaged drug; provided that this clause shall not apply to defendants' repacking New Drugs for bona fide sales in intrastate commerce;

(d) repacking or causing to be repacked any article of drug which bears on its label or labeling the statement "PROFESSIONAL SAMPLE—NOT TO BE SOLD," "Complimentary Package," "Physicians' Sample," or any similar statement, into other containers for any purpose, or otherwise altering, mutilating, destroying, obliterating, or removing the whole or any part of the package or label of said article of drug. Said physicians' sample drugs must be distributed by defendants only in the intact original manufacturer's packages or containers.

(e) causing prescription drugs while held for sale after shipment in interstate commerce to be repacked unless such repacked drugs comply with all of the conditions of the exemption regulations 21 C.F.R. 1.106(b); except that the mere difference in color in labeling used by defendants shall not be deemed a violation of this injunction so long as such labeling is clearly legible;

(f) causing drugs which are represented to be composed wholly or partly of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, to be repacked while held for sale after shipment in interstate commerce, unless certificates or releases applicable to such repacked drugs are issued pursuant to 21 U.S.C. 357;

(g) selling, distributing, repacking or relabeling drugs which bear labels containing expiration dates that have expired; and

(h) holding or storing or causing to be held or stored any drug after shipment in interstate commerce, or introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any drug which has been held or stored or caused to be held or stored by the defendants unless and until;

(i) the methods used in, and the facilities and controls used for the holding or storing of any such drug conform to and are operated and administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of the Federal Food, Drug and Cosmetic Act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess; and

(ii) any establishment in which drugs are stored or held for resale in original containers is physically separated from any establishment in which drugs are repacked or relabeled or held for repacking or relabeling by defendants;

(iii) records are established showing the name, quantity, and date of receipt of each lot or batch of drug obtained by the defendants and the name and address of the person from whom obtained;

(i) repacking or relabeling or causing to be repacked or relabeled any drug after shipment in interstate commerce, or introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce any drug which has been repacked or relabeled by defendants, unless and until

(i) the facilities and controls used for the holding or repacking of any such drug conform to and are operated and administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of the Federal Food, Drug and Cosmetic Act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess; and

(ii) records are established showing the name, quantity, control number and the date of receipt of each lot or batch of drug obtained by the defendants for repacking and the name and address of the person from whom obtained;

(iii) repacking and relabeling records are maintained so that each lot or batch of a drug repacked and relabeled by the defendants is so identified in the records as to enable the complete repacking and relabeling history of each package of drug to be determined; and

(iv) any establishment in which drugs are repacked or relabeled or held for repacking or relabeling by defendants is physically separated from any establishment in which drugs are stored or held for resale in original containers;

(j) denying to representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare free access, in accordance with applicable statutes and regulations, to all records, facilities, and controls pertaining to (1) the receipt of all drugs by the defendants, (2) the repacking and relabeling of all lots or batches of drugs, and (3) the distribution of all lots or batches of drugs whether interstate or intrastate.

8564. **Ease ointment.** (F.D.C. No. 50423. S. No. 63–569 A.)

QUANTITY: 3,042 2-oz. tubes at Las Vegas, Nev.

SHIPPED: 7–22–63, from North Hollywood, Calif., by Life Laboratories, Inc.

LABEL IN PART: (Tube) "Ease * * * Directions * * * Caution * * * Mfg. by the Health Research Division of Lovelite Cosmetics, Inc. Las Vegas, Nevada."

RESULTS OF INVESTIGATION: The article had been manufactured by Lovelite Cosmetics, Inc., and shipped in bulk to Life Laboratories, Inc., North Hollywood, Calif. There it was packed into tubes that had been prelabeled by Lovelite Cosmetics, Inc., and thereafter returned to Lovelite Cosmetics, Inc.

LIBELED: 8–12–64, Dist. Nev.; libel amended 12–2–64.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment having the natural healing ability to relieve hemorrhoids (piles), and that it had been proven to be a blessing to hemorrhoid sufferers; 502(f)(2)—the labeling failed to bear the warning statement required for rectal preparations for external use "In case of rectal bleeding, consult physician promptly"; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: On 9–11–64, Lovelite Cosmetics, Inc., Las Vegas, Nev., filed a claim and an answer denying that the article was misbranded. On 12–2–64, the libel was amended to add the above charge that the article was a new drug. On 3–24–65, the claimant consenting without admitting the allegations in the amended libel, a decree of condemnation was entered and the article was ordered destroyed.

8565. **EK–25 tablets.** (F.D.C. No. 49369. S. No. 32–106 X.)

QUANTITY: 1 2,500-tablet jar at Phoenix, Ariz.

SHIPPED: 6–10–63, from Denver, Colo., by Western Research Laboratories.

LABEL IN PART: (Jar) "EK–25."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 26.2 mg. of hydrochlorothiazide per tablet.

LIBELED: 9–30–63, Dist. Ariz.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: On 11–26–63, Western Research Laboratories, Denver, Colo., claimant, filed an answer denying that the article was a new drug. On 6–29–64, the Government served written interrogatories on the claimant. On 4–7–65, there was entered a consent decree of condemnation and destruction which included a statement to the effect that the claimant consented, without admitting any of the allegations specified in the libel, for the reason that the claimant had discontinued the manufacture and distribution of the article.

8566. Marla contact lens wetting solution. (F.D.C. No. 50890. S. No. 10–628 A.)

QUANTITY: 12 4-oz. btls. at Washington, D.C.

SHIPPED: 8–21–64, from Buffalo, N.Y., by Santa Pharmaceuticals, Inc.

LABEL IN PART: "Marla Antiseptic Wetting and Soaking Solution for Contact Lenses * * * Bacteriacidal * * * Contains: Phenoxynate Manufactured in U.S.A. by Santa Pharmaceuticals, Inc., Buffalo 16, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable micro-organisms.

LIBELED: 12–29–64, Dist. Columbia.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it was purported and represented to possess; 502(a)—the label statements "Antiseptic" and "Bacteriacidal" were false and misleading; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 4–5–65. Consent—destruction.

DRUG FOR VETERINARY USE

8567. Phenylbutazone veterinary preparations. (F.D.C. No. 50944. S. Nos. 24–224/5 B.)

QUANTITY: 4 100-tablet btls. and 4 individually ctnd. 50-cc. vials, at Hot Springs, Ark.

SHIPPED: 10–21–64, from Hialeah, Fla., by Zirin Laboratories International, Inc.

LABEL IN PART: (Btl.) "Phenylbutazone V.C.T. Phenylbutazone 1 Gm. Tablets. Dosage—for veterinary use only Distributed by Zirin Laboratories Intl., Inc., Miami 48, Florida. Indications: For the treatment of bursitis, osteoarthritis, arthritis, rheumatism, chronic hip pains and chronic pain in trapezius muscles"; and (vial and ctn.) "Butasave for veterinary use only (Phenylbutazone) injectable each cc. contains phenylbutazone—200 Mg—Distributed by Zirin Laboratories Intl., Inc., Miami 48, Florida. Dosage—Not for use in food animals."

LIBELED: 2–8–65, W. Dist. Ark.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application was effective with respect to such drugs.

DISPOSITION: 3–17–65. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

8568. Various prescription drugs. (F.D.C. No. 45955. S. Nos. 84–245/58 R.)

QUANTITY: 18,434 containers of drugs, at Bronx, N.Y., in possession of Isaac Zonana and Bronx Drug Co., Inc.

SHIPPED: On unknown dates, from various firms outside the State of New York.

LABEL IN PART: "Caution: Federal law prohibits dispensing without prescription," and the words "Complimentary," "Professional Sample," "Physician's Sample—Not To Be Sold," or "Sample—Not To Be Sold."

LIBELED: 6–21–61, S. Dist. N.Y.; libel amended 12–5–61.

CHARGE: Original libel and amended libel, 502(a)—while held for sale, the statements "Complimentary," "Physician's Sample—Not To Be Sold," "Sample—Not To Be Sold," "Professional Sample," and similar wording borne on the labels of a number of the articles were false and misleading as applied to such articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

Amended libel only, 502(a)—the labeling of a number of the articles was misleading as applied to the articles which were not suitable for use after their expiration date had expired; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use after their expiration date; and 502(l)—a number of the articles were represented as drugs composed wholly or partly of a kind of penicillin or bacitracin, or a derivative thereof, and they were not from a batch with respect to which a certificate was effective since the drugs had passed their effective expiration dates.

DISPOSITION: On 7–6–61, the claimant, Isaac Zonana, Bronx, N.Y., filed an answer denying that the articles were misbranded and, on 7–14–61, the claimant served written interrogatories upon the Government. On or about 8–31–61, the Government filed answers to the claimant's written interrogatories and, thereafter, served written interrogatories upon the claimant. Subsequently, the claimant filed a motion for summary judgment and the Government filed a motion to strike claimant's answer for failure to answer written interrogatories. On 7–30–62, the court handed down the following opinion relating to the claimant's and Government's motions:

BRYAN, *District Judge:* "This is an action brought by the United States under § 304 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 334[1] against certain articles of drugs alleged to be misbranded while held for sale after shipment in interstate commerce and thus subject to seizure and condemnation.

"The action was commenced by the filing of a libel of information pursuant to § 304 of the Act (21 U.S.C. § 334). Pursuant to monition issued by this court the United States Marshal for this district seized the drugs which were in the possession of Isaac Zonana who is a packager and wholesaler of drugs licensed by the State of New York. The drugs are now being held in the Marshal's custody under the jurisdiction of this court.

"The drugs seized may be dispensed only by prescription. They were originally placed in interstate commerce by drug manufacturers as physician samples. The labels on the libeled drugs bear typically such statements as "complimentary," "physician's sample—not to be sold," "professional sample," "sample—not to be sold." In its original libel the Government's sole claim was that these drugs, marked in this manner, were misbranded because they were in the possession of a repacker of drugs who intended to repackage them and to sell them to pharmacists who would eventually resell to the ultimate consumer.

"Zonana, the claimant and owner of the drugs at the time of seizure, has moved for summary judgment dismissing the original libel and to have the seized articles returned on the ground that as a matter of law the drugs

[1] § 334. Seizure-Grounds and jurisdiction.

(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.

are not misbranded within the meaning of the statute.[2] At the same time the Government cross-moved to amend its libel and to strike claimant's answer for failure to answer interrogatories served upon him by the Government. The cross-motion to amend was granted on consent of the claimant and the Government amended its libel to add numerous other quite different claims of misbranding which, if established, make them subject to seizure and condemnation under 21 U.S.C. § 334. Claimant has served a timely answer to the amended libel.

"Under these circumstances, claimant's motion will be considered as one for partial summary judgment directed to that portion of the amended libel which alleges misbranding under 21 U.S.C. § 352(a) solely because of the legends appearing on the labels of packages in which the drugs were contained, such as "Sample—not for sale".

"21 U.S.C. § 352(a) provides that a drug shall be deemed to be misbranded "[i]f its labeling is false or misleading in any particular".

"The Government takes the position that the labeling of these drugs is false and misleading because when they came into the possession of claimant wholesaler for packaging and sale to retail pharmacists they were no longer 'complimentary' or 'samples' or 'not to be sold', and that they therefore must be deemed to be misbranded within the meaning of the statute. The Government does not deny that prior to the time when they came into the wholesaler's possession the drugs were in fact complimentary or physicians' or professional samples and were properly labeled in all respects. It affirmatively charges that it was the intention of the claimant to remove these labels and repackage without the allegedly offending language. Its theory on this phase of the case is that the drugs became misbranded when they came into possession of a repacker for repackaging and resale to retailers, under labels eliminating the legends designating them as 'samples'.

"In my view the Government's position cannot be sustained.

"In determining the scope of this statute and applying it to specific cases, the court must consider the purpose of the statute. As Mr. Justice Frankfurter said of the Act in his dissent in *United States* v. *Sullivan*, 332 U.S. 689, 705 (1948), 'its meaning can hardly be so clear that he who runs may read, or that even he who reads may read.'

"The Supreme Court has said on numerous occasions that the statute was designed primarily to protect the ultimate consumer from dangerous products. *United States* v. *Sullivan*, *supra*. The original Act of 1906 'was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles * * *. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.' *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). See also *Hipolite Egg Co.* v. *United States*, 220 U.S. 45 (1911); *McDermott* v. *Wisconsin*, 228 U.S. 115 (1913); *United States* v. *Walsh*, 331 U.S. 432 (1947); *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950); *62 Cases of Jam* v. *United States*, 340 U.S. 593 (1951).

"In the *62 Cases of Jam* case the court pointed out—

> 'In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.' (p. 600).

"When viewed in this light it is apparent that the Government's claim of misbranding under 21 U.S.C. § 352(a) is beyond the permissible bounds of the

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[2] Claimant mistakenly has moved for summary judgment under Rule 58(c) of the Admiralty and Maritime Rules. Though an in rem libel action under 21 U.S.C. § 334 is brought on the admiralty side the ordinary rules of civil procedure apply to the proceedings after the initial filing and seizure of the articles. See *United States* v. *Arizona Canning Co.*, 212 F. 2d 532 (10 Cir. 1954); *Alberty Food Products Co.* v. *United States*, 185 F. 2d 321 (9 Cir. 1950).

Therefore claimant's motion is treated as one for summary judgment under Rule 56(c), F.R.C.P.

Act. In its original libel and under that portion of the amended libel based upon § 352(a) the Government has made no claim that the seized drugs were deleterious or harmful to health in any respect because of the legends on the labels reading typically 'Physician's Sample—not to be sold' or 'Complimentary'. There is no claim that the drugs differ in any manner from drugs not bearing these legends or that the rest of the label does not conform to all other statutory requirements for proper dispensing and safe use.

"On the contrary, the Government concedes that while these drugs were in the possession of the manufacturer, the original distributors, and physicians, they were not misbranded within the meaning of the section. It does not charge that the wholesaler has sold or intends to sell or distribute the drugs with these labels on them, and, in fact, does not deny that it is intended to repackage them in larger quantities with different and entirely proper labels before resale.

"Thus the charge of misbranding is directed solely to the period when the drugs were to be in the possession of the wholesaler for what have not been shown to be other than legitimate and proper purposes. No one is likely to be misled by these labels nor can they do any harm to the health or safety of the consuming public.

"The only case directly in point which has been brought to my attention is an unreported decision in the District Court for the District of New Jersey (*United States* v. *Articles of Drugs*, Docket Nos. 497–61, 504–61, decided by Judge Meany on October 9, 1961). There summary judgment was granted from the bench dismissing libels making the same charge of misbranding as is made in the case at bar as not being within the scope of the statute. In my view that holding is correct. The same result must be reached here.

"The references in the Government's memorandum to 'a nationwide investigation' by the Food and Drug Administration of the use of sample drugs and to statements to the press by the Commissioner advising of dangers and abuses, do not affect this conclusion. Plainly, these references have no evidentiary value. But beyond this it is not charged that the claimant here was guilty of any such abuses and none of them have been brought home to him.

"Moreover, the Act provides adequate remedies, both civil and criminal, for dealing with persons who place deleterious or dangerous articles of drugs in commerce if such facts should come to the Government's attention. The fact that some abuses may exist does not justify extending the scope of this statute providing drastic remedies and with possible penal consequences beyond the meaning and intent of the language which it uses.

"Claimant's motion for partial summary judgment dismissing paragraph IV–1 of the amended complaint is granted. The Government's motion under Rule 33, F.R.C.P., to strike claimant's pleading for failure to serve answers to interrogatories is denied on the condition that within twenty (20) days from the date of the order to be entered on this decision claimant serve answers to the interrogatories.

"Settle order on notice."

On 9–28–62, an order was entered in accordance with the foregoing opinion, after which the claimant filed answers to the Government's written interrogatories. On or about 2–19–63, the claimant served additional written interrogatories upon the Government which were subsequently answered by the Government. On 3–13–63, a subpoena was issued addressed to the Food and Drug Administration, requesting the production of certain records, papers, and books. The Government filed a motion to quash the subpoena and thereafter, on 4–23–63, after considering the briefs and arguments of counsel, the court decided that the subpoena was too broad and should be limited to require the production of only those records, papers, and other documents relating to the drugs under seizure and the results of analysis of the post-seizure samples of such drugs, subject, however, to a ruling on whether any of such records, papers, etc., were privileged under *Hickman* v. *Taylor* 249 U.S. 495 (1947) in the event such privilege was later claimed.

On 11–22–63, the court issued an order directing the consolidation for trial of this seizure action with the injunction action previously reported in Drug and Device Notice of Judgment No. 8563. Such order also directed that certain drugs under seizure should be returned to the claimant but enjoined the claimant pending determination of the consolidated action, (1) from repacking the returned drugs which were in the original manufacturer's containers or doing any act with respect to such returned drugs which would result in their adulteration or misbranding, and (2) from distributing such drugs except in the intact original manufacturer's containers.

On 11–10–64, with the consent of the claimant and the Government, the court entered an order dismissing the seizure action on the following conditions:

1. That those articles of drug under seizure which, because of the passage of time, or failure to bear adequate directions for use, or otherwise, were adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, be condemned and destroyed;

2. That all other articles of drug under seizure be returned by the United States marshal to the claimant, Isaac Zonana; and

3. That the claimant, Isaac Zonana, pay the expenses of segregating the seized articles of drug into the two classifications above-described.

8569. Antibiotic discs. (F.D.C. No. 51123. S. No. 37–826 B.)

QUANTITY: 25 pkgs., each containing 50 clear plastic 1-unit envelopes, at Newburgh, N.Y.

SHIPPED: 12–8–64, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 32 percent of the amount of erythromycin declared on its label.

LIBELED: On or about 4–23–65, S. Dist., N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(l)—the article purported to be and was represented as a drug composed in part of antibiotic drugs and was not from a batch with respect to which a certificate or release was in effect.

DISPOSITION: 6–21–65. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

8570. Various drugs. (F.D.C. No. 45931. Inj. No. 499. S. Nos. 56–489/500 R, 57–061/80 R, 57–141/78 R.)

QUANTITY: 81¾ ctns., 6 cases, and 8 vials, of various drugs, at Jersey City, N.J., in possession of Fall Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Caution: Federal law prohibits dispensing without prescription," "PROFESSIONAL SAMPLE—NOT TO BE SOLD," "Professional Sample," "Complimentary Packages," "Physicians Sample," and "Complimentary Package."

RESULTS OF INVESTIGATION: The articles purported to be manufactured by various firms outside the State of New Jersey, and were received by the dealer on unknown dates from various drug handlers. Some of the articles had been repacked by Fall Drug Co., and some of the articles had not been repacked.

LIBELED: 6–9–61, Dist. N.J.; libel amended 6–13–61.

CHARGE: 502(a)—while held for sale, the statements "PROFESSIONAL SAMPLE—NOT TO BE SOLD," "Professional Sample," "Complimentary Packages," "Physicians Sample," "Complimentary Package," and similar wording borne on the labels of a number of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—a number of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) a statement of the quantity of contents; 502(e)(1)—the labels of a number of the articles failed to bear the common or usual name of the drugs; 503(b)(4)—a number of the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and, in the case of the prescription drugs, such drugs were not exempt from that requirement since their labels failed to bear an identifying lot number as required by regulations.

DISPOSITION: The articles were claimed by Martin Fall, Jersey City, N.J., on 8–21–61, and on the same date the claimant filed an answer denying the misbranding charges and served written interrogatories on the Government; thereafter, the Government filed answers to the claimant's written interrogatories. On 3–28–62, the claimant filed his answers to the Government's written interrogatories which had previously been served on him. On 3–2–65, pursuant to stipulation of the parties, the court vacated the claim of Martin Fall with respect to the drugs under seizure which were repacked, not physicians' samples, not in their original packaging, failed to bear a manufacturer's control number, outdated (expiration date has passed), were deteriorated (as determined by organoleptic, chemical, or analytical examination), were investigational new drugs, drugs which had been withdrawn from the market by the manufacturer, new drugs with respect to which approval of the NDA had been withdrawn, drugs not accompanied by the full disclosure information required by regulations, drugs in a package which contained two or more different drugs, drugs in a package which bore only a portion of the original physician's sample label, and placebos; and the court ordered that such drugs be condemned and destroyed. As to the other drugs to which the claim of Martin Fall remained applicable, and consisting of drugs in original packages and bearing various sample legends in their labeling, the court ordered that such drugs be returned to the claimant.

The court ordered further that the claimant was enjoined from repacking the physician-sample drugs into other containers for sale or otherwise altering, mutilating, destroying, obliterating or removing the whole or any part of the labeling, or of doing any other act with respect to the physician-sample drugs while they were held for sale which resulted in their being adulterated or misbranded. It was ordered also that the physician-sample drugs may be distributed by the claimant only in the intact original manufacturer's packages or containers.

8571. Pas tablets. (F.D.C. No. 50838. S. No. 89–936 A.)

QUANTITY: 2 drums of 25,000 tablets each, and 1 drum of 20,000 tablets, at Philadelphia, Pa.

SHIPPED: 9–25–64, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Drum) "Zenith Laboratories, Inc. Englewood, New Jersey 25 M Pas Tablets, 0.5 gm. Each tablet contains: Para Amino Salicylic Acid 0.5 gm."

RESULTS OF INVESTIGATION: Analysis showed that the article contained essentially the declared amount of para-aminosalicylic acid, and that the article failed to disintegrate after 6 hours when tested according to the method set forth in the United States Pharmacopeia XVI for enteric-coated tablets.

LIBELED: 11–25–64, E. Dist. Pa.

CHARGE: 501(b)—when shipped, the article purported to be a drug, "Aminosalicylic Acid Tablets," the name of which is recognized in an official compendium, namely, the United States Pharmacopeia, and its quality fell below the standard set forth in such compedium; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement, since the article was a prescription drug and its labeling failed to bear, as required by regulations, adequate information for its use, including effects and any relevant hazards, contraindications and side effects and precautions under which practitioners could use the drug safely and for the purposes for which it was intended, including all the purposes for which it was advertised or represented in its labeling; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dipsensing without prescription."

DISPOSITION: 1–27–65. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

8572. Amphetamine-containing drugs. (F.D.C. No. 48831. S. No. 18–259 V.)

QUANTITY: Unknown quantities of *amphetamine-containing drugs*, at Houston, Tex., in possession of William L. (Tex) Palmer, Sr., and William L. Palmer, Jr.

SHIPPED: Prior to 3–13–63, from outside the State of Texas.

LIBELED: 3–13–63, S. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement, since they were prescription drugs in possession of persons not lawfully engaged in distributing or dispensing drugs.

DISPOSITION: On 4–15–63, William L. (Tex) Palmer, Sr., filed an answer applicable to the drugs in his possession, in which he denied that such drugs were misbranded, and alleged that he had a State permit to distribute the drugs on the wholesale level.

On 12–4–63, a default decree of condemnation and destruction was entered against the following quantities of amphetamine sulfate tablets which were seized in the possession of William L. Palmer, Jr.: 2 cases of 18 1,000-tablet bottles, 3 cases of 17 1,000-tablet bottles, and 1 case of 10 1,000-tablet bottles.

*See also Nos. 8561–8564, 8568, 8570, 8571.

On 1–28–64, with the consent of William L. (Tex) Palmer, Sr., judgment of condemnation and destruction was entered against the portion of the amphetamine drugs seized in his possession whose labeling failed to bear or contain adequate information under which practitioners, licensed to administer the drugs could use the drugs safely and for the purpose for which they were intended. On 4–19–65, the case against the remaining drugs, which had been seized in the possession of William L. (Tex) Palmer, Sr., and charged to be misbranded under 502(f)(1), as described above, came on for trial and, at the conclusion of the trial, the court found for the Government. On 5–7–65, the court entered an order for condemnation and destruction of such drugs..

8573. **Amphetamine drugs.** (F.D.C. No. 50947. S. No. 24–613 B.)

QUANTITY: 30,000 tablets or capsules, at St. Louis, Mo., in possession of Charles Marshall.

SHIPPED: On or before 2–11–65, from outside the State of Missouri.

LIBELED: 2–11–65, E. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and the article was not exempt from such requirement.

DISPOSITION: 4–30–65. Default—destruction.

8574. **Amphetamine drugs.** (F.D.C. No. 51130. S. Nos. 25–433/4 B.)

QUANTITY: Unknown quantities of amphetamine tablets and capsules, at Hayti, Mo., in possession of Boyd Curtis and Doyle Nance.

SHIPPED: On unknown dates, from outside the State of Missouri.

LIBELED: 3–30–65, E. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use, and the articles were not exempt from such requirement, since they were in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since they were not to be dispensed upon prescription as required by regulations.

DISPOSITION: 5–3–65. Default—delivered to the Food and Drug Administration.

8575. **Amphetamine tablets and capsules.** (F.D.C. No. 50953. S. Nos. 14–513/16 B.)

QUANTITY: 103,808 tablets, at Denver, Colo., in possession of Reinold L. Swanson, and 43,622 tablets and 5,000 capsules, at Denver, Colo., in possession of Jerome V. Whisler and Julia A. Whisler.

SHIPPED: 2–24–65, from outside the State of Colorado.

LIBELED: 2–25–65, Dist. Colo.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since the articles were in the possession of a person or persons who were not legally and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since such articles were not to be dispensed upon prescription.

DISPOSITION: 4–7–65. Default—destruction.

8576. Dipyrone preparations. (F.D.C. No. 50566. S. Nos. 82–624/6 A.)

QUANTITY: 239 btls., each containing 100 320-mg. tablets, 16 boxes, each containing 50 2-ml. ampuls, and 30 boxes, each containing 25 2-cc. ampuls, at Secaucus, N.J.

SHIPPED: (Tablets) 6–26–64 and 7–10–64, (ampuls) 7–21–64, from Rensselaer, N.Y., by Winthrop Laboratories, Div. of Sterling Drug, Inc.

LABEL IN PART: (Btl.) "Novaldin brand of dipyrone * * * Caution: Federal law prohibits * * * Winthrop Laboratories, New York, N.Y. Division of Sterling Drug, Inc. Usual dose: 1 tablet Read accompanying circular," (ampul) "Novaldin Brand of Dipyrone," (pkg. insert, 239 btls. and 16 boxes) "Novaldin Brand of Dipyrone Oral and Injectable Analgesic," (ampul) "Injection * * * Pydirone Brand of Dipyrone * * * Supplied by Rx Products Division Breon Labs., Inc., N.Y. 18," (pkg. insert) "Pydirone Brand of Dipyrone * * * Description."

LIBELED: 9–4–64, Dist. N.J.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since they were prescription drugs and their labeling failed to contain all of the information required by regulations.

DISPOSITION: 3–29–65. Winthrop Laboratories, Div. of Sterling Drug, Inc., claimant, having filed an answer to the libel and having subsequently withdrawn its claim and answer, judgment of condemnation and destruction was entered.

8577. Methischol products. (F.D.C. No. 50107. S. Nos. 893/6 A.)

QUANTITY: 3,789 100-capsule btls., 82 250-capsule btls., 94 500-capsule btls., and 192 1,000-capsule btls., of *Methischol;* 340 16-oz. btls. and 6 1-gal. btls., of *Methischol syrup;* 61 100-tablet btls., of *Methischol;* and 72 16-oz. btls., of *Beta-Methischol syrup,* at Atlanta, Ga.

SHIPPED: 2–14–64, 3–5–64, and subsequent thereto, from Yonkers, N.Y., by U.S. Vitamin & Pharmaceutical Corp.

LABEL IN PART: (Btl.) "Methischol Each Capsule provides Choline Dihydrogen Citrate 277 mg. Methionine 110 mg. Inositol 83 mg. Vitamin B_{12} (Cobalamin Concentrate) 2 mcg. Desiccated Liver 56 mg. Liver Concentrate 30 mg.," "Syrup Methischol," "Enteric Coated Tablets Methischol," "Syrup Beta-Methischol"; (btls. additionally labeled) "U.S. Vitamin & Pharmaceutical Corp. Arlington-Funk Labs., Division New York, N.Y."

LIBELED: 5–4–64, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use, since the articles were offered for the treatment and prevention of fatty infiltration and fatty degeneration of the liver, which conditions could not be diagnosed by the layman, nor could the progress of the conditions and collateral measures necessary to the recommended treatment be determined by the layman.

DISPOSITION: 4–19–65. The U.S. Vitamin & Pharmaceutical Corp., claimant, having filed an answer to the libel and having subsequently withdrawn its claim and answer, judgment of condemnation and destruction was entered.

8578. Mephenesin tablets, Cin tablets, tolazoline tablets, and digitoxin tablets. (F.D.C. No. 49931. S. Nos. 18–841/3 A, 18–845 A.)

QUANTITY: 7 500-tablet btls. of *mephenesin tablets*, 26 1,000-tablet btls. of *Cin tablets*, 3 1,000-tablet btls. of *tolazoline tablets*, and 8 1,000-tablet btls. of *digitoxin tablets*, at Buffalo, N.Y., in possession of Ziegler Pharmacal Corp.

SHIPPED: 1–22–63, from Edgewater, N.J. (*mephenesin tablets*); 8–21–62, from Auburn, Mass. (*Cin tablets*); 5–11–60, from Philadelphia, Pa. (*tolazoline tablets*); 1–17–62, from Edgewater, N.J. (*digitoxin tablets*), which were shipped in bulk and repacked by the dealer into bottles.

LABEL IN PART: (Btls.) "Control No. 378 Mephenesin 7.7 Gr. (Myanesin or Toloxya) Contra-Indications: * * * Caution * * * Distributed and sold exclusively by Ziegler Pharmacal Corp. Buffalo 2, N.Y.," "8002 Cin Tablets Cincophen 2½ grs. Sodium Salicylate 2½ grs. Iodized Lime ½ gr. Ext. Colchium Corm ¼ gr. * * * Warning * * * Caution * * * Distributed * * * by Ziegler Pharmacal Corp. Buffalo 2, N.Y.," "12272 Tolazoline U.S.P. 25 Mg. Dosage: * * * Caution * * * Distributed * * * by Ziegler Pharmacal Corp. Buffalo 2, N.Y.," "2563 Digitoxin U.S.P. 0.1 Mgm. Warning * * * Caution * * * Distributed * * * by Ziegler Pharmacal Corp. Buffalo 2, N.Y."

LIBELED: 4–6–64, W. Dist. N.Y.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since they were prescription drugs and their labeling failed to bear adequate information for use including dosages, frequency of administration and any relevant hazards, contraindications, and side effects and precautions under which practitioners could use the drugs safely and effectively for the purposes for which they were advertised or represented in their labeling, as required by regulations.

DISPOSITION: 4–15–65. Default—destruction.

8579. Nemase tablets. (F.D.C. No. 48980. S. Nos. 35–559/60 V.)

QUANTITY: 2,616 vials, each containing 100 tablets, at Minneapolis, Minn., in possession of Northrup Pharmaceutical Co.

SHIPPED: 10–18–62 and 12–11–62, from Long Island City, N.Y., by Robin Pharmacal Corp., and Nysco Laboratories, Inc.

LABEL IN PART: "Nemase Each Tablet Contains: Niacin 50 mg. Ascorbic Acid 100 mg. Thiamine Mononitrate 100 mg. Hyoscine Hydrobromide 1/300 gr. Caution: * * * Distributed by Northrup Pharmaceutical Co. Minneapolis, Minn. * * * Action & Indications."

ACCOMPANYING LABELING: Detail cards reading in part "Nemase Vasodilator Spasmolitic Composition * * * Action & Indications * * * Northrup Pharmaceutical Company."

LIBELED: 6–4–63, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article, namely, the vial label and the detail cards described above, contained statements which represented and suggested that the article was adequate and effective for the treatment of multiple sclerosis, spastic paraplegia, cerebral palsy, Parkinson's disease, peripheral vascular diseases, cerebrovascular insufficiency, and for energy production, which statements were false and misleading, since the article was not adequate and effective for such purposes; and 502(f)(1)—the labeling of the article failed to bear adequate directions

for use, and adequate directions for use could not be written for the conditions for which it was offered or for any other conditions, either for the layman or for a physician.

DISPOSITION: On 7–10–63, Northrup Pharmaceutical Co., claimant, filed an answer denying that the article was misbranded. On 8–26–63, the Government served written interrogatories upon the claimant. On 10–15–63, the claimant served answers to the Government's written interrogatories and, on 4–10–64, the claimant filed supplementary answers to the Government's written interrogatories. On 7–14–65, the claimant having withdrawn its claim and answer, the court entered a decree of condemnation and destruction.

8580. Nepco-Zyme. (F.D.C. No. 50859. S. No. 127–998 A.)

QUANTITY: 293 10-cc. vials at Ferndale, Mich.

SHIPPED: Arginase, the active ingredient of the article, was shipped on 12–4–63, from Freehold, N.J.

LABEL IN PART: "Nepco * * * Nepco-Zyme Multiple Dose Each cc contains 5 units* of the manganese activated enzyme arginase, sodium chloride C.P.O. 85%, Glycine 0.02 molar, thimerosal 1:10,000, and water for injection. * * * Caution: * * * Taylor New England Pharmacal Co. Michigan."

ACCOMPANYING LABELING: Inserts reading in part "Nepco-Zyme Description * * * Physiology * * * Safety Factor."

RESULTS OF INVESTIGATION: The article had been manufactured in Detroit, Mich., for New England Pharmacal Co., Wyandotte, Mich., from arginase shipped as above. Thereafter, New England Pharmacal Co. shipped the article, labeled as above, to the dealer.

LIBELED: 12–3–64, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective in the treatment of all inflammatory conditions, including arthritis (rheumatoid, osteo, psoriatic, and gout), and in the treatment of inflammation associated, with bursitis, low back pain, torticollis, fibrositis, cellulitis, tendonitis, sinusitis, post-operative tissue reaction, episiotomy, psoriasis, herpes zoster, bruises, sprains, phlebitis, and thrombophlebitis; and 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from such requirement, since it was a prescription drug which was a new drug subject to 505 and its labeling bearing information for the use of said drug was not labeling authorized by an effective new-drug application.

DISPOSITION: 5–3–65. The New England Pharmacal Co., having appeared as claimant and filed an answer, and the Government having thereafter filed a motion for judgment on the pleadings, the court adjudged the article to be misbranded under 502(f)(1), as alleged in the libel, and entered a decree of condemnation and destruction.

8581. Zinsep compound antacid. (F.D.C. No. 50008. S. No. 57–188 A.)

QUANTITY: 88 individually ctnd. 11-fl.-oz. btls., at Kansas City, Mo.

SHIPPED: 10–17–63, from Kansas City, Kans., by Union Pharmacal Co.

LABEL IN PART: (Btl.) "Zinsep Compound Antacid Gas Eliminant * * * A gentle laxative Active Ingredients * * * Caution * * * Manufactured by Union Pharmacal Co. P.O. Box 8105 Kansas City 12, Mo."

ACCOMPANYING LABELING: Package inserts entitled "What Users Say."

LIBELED: 4–28–64, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for the prevention and treatment of stomach ulcers, stomach pains, upset stomach, intestinal gas, and other long-standing stomach conditions; and 502(f)(1)—the labeling failed to bear adequate directions for use for the conditions for which the article was offered since adequate directions for lay use cannot be written for such conditions.

DISPOSITION: 4–29–65. Consent—claimed by William J. B. Mayor, Kansas City, Kans., and relabeled.

8582. Niagara vibrating devices. (F.D.C. No. 50989. S. No. 123–388 A.)

QUANTITY: 9 chairs, 5 hand units, and 11 suitcase models, each containing pads and timers, plus hand units, at Fairmont, Minn., in possession of Niagara of Southern Minnesota.

SHIPPED: Between 8–4–64 and 11–20–64, from Brocton, N.Y.

RESULTS OF INVESTIGATION: The articles consisted of electrical devices containing vibratory mechanisms and/or units for the production of heat, which devices were intended for home application to the body.

LIBELED: 1–26–65, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment of arthritis, swelling in the joints, stiff fingers, varicose veins, nervous tension, crooked knees, bursitis, poor circulation, sore back, and heart patients; to relieve the strain on the heart, bad back, headaches and hangover headaches, sinus, bowel trouble, sciatic conditions, body elimination, colitis, colon spasm, ulcers, multiple sclerosis, and women's monthly trouble; and that the use of the device would increase circulation right around the heart; provide massaging action that penetrates clear through your body; help the heart to work easy and make it easier for the heart; and induce better bowel regularity; which were the conditions and purposes for which the articles were recommended in oral statements made, on 12–3–64, by Gordon Persons, sales representative for Niagara of Southern Minnesota.

DISPOSITION: 4–15–65. Default—delivered to charitable institutions.

8583. Micro-Dynameter devices. (F.D.C. No. 49778. S. Nos. 29–174/5 X, 29–942 X.)

QUANTITY: 5 devices at Topeka, Kans., and 1 device at Mulvane, Kans.

SHIPPED: On unknown dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: (Control panel) "Manufactured by Ellis Research Laboratories, Inc. Chicago * * * Model * * * Serial * * * The Ellis Micro-Dynameter," and (metal plate on device cabinet) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

RESULTS OF INVESTIGATION: Examination indicated that each device was essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude. The device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or

decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 2–20–64, Dist. Kans.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 7–8–64. Default—destruction.

8584. Various electronic devices. (F.D.C. No. 49360. S. Nos. 20–371/6 X.)

QUANTITY: 1 *ultrasound device*, 1 *electrical-frequency generator device*, 5 *electronic Magnetic Model G devices*, 1 *Auto-Electronic Radioclast device*, and 1 *Electron-O-Ray device*, at Dallas, Tex., in possession of Mrs. H. O. (Creola) Glasscock.

SHIPPED: Between 1–1–53 and 3–21–61, from Los Angeles, Calif., and Tiffin, Ohio.

RESULTS OF INVESTIGATION: Inspection of the *ultrasound device* indicated that it was an electronic high-frequency oscillator circuit of the self-rectifying type, having a pulsed-power output and a sound-head applicator which generated the ultrasound energy. The circuit was enclosed in a simulated leather case with storage space for the electrical wires and soundhead. The gray "hammertone" panel contained a milliampere meter, an internal timer with automatic shutoff, a tuning control, and one 10-position power control. The soundhead was connected to the instrument circuit through a flexible coaxial cable.

Inspection of the *electrical-frequency generator device* indicated that it was a small compact box containing an electrical circuit for the production of various-size-wave electrical frequencies. The front panel contained the frequency and intensity controls, light, and terminals. The unit included treatment pads, cords, and electrodes.

Inspection of the *Electronic Magnetic Model G devices* indicated that they were suitcase-type units which, on opening, revealed the control panel and storage, power, and magnetic control switches and an electronic control dial. The two electronic electrodes were rectangular metal strips and the magnetic electrodes were two coils of wire enclosed in a metal housing approximately 6 inches in diameter. The electronic electrodes applied 7.2-cycles-per-second current to the body, and the magnetic coils operated on 220 cycles per second.

Inspection of the *Auto-Electronic Radioclast devices* indicated that they were wooden cabinets containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of three dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present, and additional dials purportedly determined the intensity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determined the location of the disease in the body.

Inspection of the *Electron-O-Ray device* indicated that it was a console desk-type diagnostic and treatment unit with a slide-out counter. The counter contained the reaction plate which was rubbed by the operator. Above this counter top was a vertical control panel containing meters, dials, switches, and female electrode terminals. The dials were used to measure the vibratory rate of the disease, determine which part of the body was diseased, and the intensity of the ailment. Other knobs controlled the production of various frequency and other electrical outputs to the patients electrodes. The electronic circuits consisted of a power supply amplifier, and variable frequency generator.

LIBELED: 10–10–63, N. Dist. Tex.

CHARGE: *Ultrasound device* and *electrical-frequency generator device*, 502(f)(1)—while held for sale, the labeling of the devices failed to bear adequate directions for use and they were not exempt from such requirement, since they were prescription devices and they were not in the possession of a practitioner licensed by the laws of the State of Texas to use or order the use of such devices, and their labels failed to bear the prescription legend "Caution: Federal law restricts this device to sale by or on the order of a physician," as required by regulations.

Electronic Magnetic Model G devices, *Auto-Electronic Radioclast device*, and *Electron-O-Ray device*, 502(f)(1)—while held for sale, the labeling of the devices failed to bear adequate directions for use in the diagnosis or treatment of any disease conditions, and it was not feasible to devise any directions for use because the devices were worthless for any medical purposes.

DISPOSITION: 11–20–64. Default—delivered to the Food and Drug Administration.

8585. Miracle Water Klearex water refiner device. (F.D.C. No. 51010. S. No. 100–089 A.)

QUANTITY: 35 devices, at San Francisco, Redwood City, and Union City, Calif., in possession of Triangle Enterprises, Inc., trading as American Consolidated Co.

SHIPPED: Prior to and after 12–21–64, from Middletown, Ohio, by Water Refining Co., Inc., to Anaheim, Calif., and subsequently reshipped to the above-listed locations.

LABEL IN PART: (Device) "Miracle Water Klearex," and (metal plate on device) "Model No. * * * Serial No. * * * Water Refining Co., Inc. Middletown, Ohio."

ACCOMPANYING LABELING: Manuals entitled "Miracle Water Klearex Owner's Manual 34030" and "Retail Salesman's Miracle Water"; booklets entitled "Sales Presentation"; and demonstration kits, containing a model water refiner and demonstration materials.

RESULTS OF INVESTIGATION: Some of the manuals were shipped by Water Refining Co., Inc., on 9–16–64, and the others were delivered by hand, by one of the company representatives, during the spring of 1964. The booklets were printed locally, by the dealer, during the summer of 1964; and the demonstration kits were shipped on an unknown date from St. Paul, Minn.

Examination showed that the device consisted of a cylinder of activated charcoal, a Dowex resin filter, and timing apparatus for automatically triggering a recharging mechanism. The device was intended for installation in the household water supply line for the purpose of filtering and treating the water delivered at the household faucets.

LIBELED: 2–17–65, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the articles would prevent illness and thus save money through fewer doctor and medicine bills, protect arthritis sufferers through treatment of waters which were taken from lime-soaked soils and which would sooner or later calcify the body with their deposits; that drinking hard water daily was the origin of several diseases, all skin problems come from bacteria-laden soap curd, water from this device was effective in preventing or curing diaper rash and cradle cap; and that the use of this device protected the user, in that it removed the chlorine used in water treatment, over-flow industrial waste, radio-active particles, detergents, algae, lignin, tanins and pyrogenic micro-organisms; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for producing, through the use of this device, an absolutely perfect water which was just like mountain spring water, for removing from the water supply all radiation, detergents, pesticides, insecticides, radio-active poisons, weed killers and disease-bearing wastes which threatened the health of millions of Americans, for preventing stomach problems due to detergent contamination of the water supply, for preventing aches and pains suffered by people about 50 years of age due to water impurities lodged in the body joints, for preventing the home water supply from going up every spring to about 8-parts-per-million of chlorine, for filtering out all bacteria in the water supply as well as the dead bacteria, for giving the homeowner a perfect water supply and for completely removing all the chlorine from the water supply and for removing the causes of diaper rash, which were the conditions and purposes for which the article was claimed and represented to be adequate and effective in an oral presentation made on 12–3–64, by a sales representative for the American Consolidated Co., of San Francisco.

DISPOSITION: 3–2–65. Consent—claimed by Triangle Enterprises, Inc., trading as American Consolidated Co.; the devices and demonstration kits were released to the Water Refining Co., Inc., Anaheim, Calif., and the labeling and literature were destroyed.

8586. Vis Vitae "Wonder Mineral" device. (F.D.C. No. 51079. S. No. 16–281 B.)

QUANTITY: 790 unlabeled glass vials, each containing approximately ⅕ oz. of rock fragments, and approximately 24 17-page pamphlets entitled "Vis Vitae (Vigor of Life) The 'Wonder Mineral'," at North Hollywood, Calif., in possession of Colonel Arthur E. Powell.

SHIPPED: On unknown date, from Zululand, South Africa.

RESULTS OF INVESTIGATION: Examination showed the article of device to consist of a small glass vial with black plastic screw-type cap, containing irregularly-shaped pieces of a light-brown rock-like mineral, ranging in size from dust to approximately 1x5x7 millimeters. In use, the device is suspended around the neck by a string, fastened to the clothing, or placed upon a diseased part of the body for alleged curative effect due to supposed radiations from the vial. The article was shipped in bulk, as described above, and repacked into the vials by the dealer.

LIBELED: 2–26–65, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling, namely, the pamphlet described above, accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for severe,

continuous headache; severe arthritis; heart trouble; asthma; broken leg; cancer; bladder pains; lumbago; thrombosis; permanently swollen neck; liver spots; face rash; angina pectoris; neuritis; knee trouble; migraine; nervous breakdown; anemia; diabetes; prostate trouble; high blood pressure; mental conditions; dropsy; bad circulation; kidney infection; terrible itching from surgical incision; cerebrospinal meningitis; rheumatic heart; hypertension; malaria; typhoid; scarlet fever; stomach trouble of long standing; tuberculosis; breathlessness; fatigue; sneezing; fever; sinus; bursitis; sore throat; colds; hemorrhoids; eczema; irregular heartbeat; poison ivy; poison oak; shingles; pain in breast; and stomach ulcers; and that use of the device would cure the sick by permeating the whole body; ease pain; improve health; give vigor to life; increase general vitality; render manual workers less tired; induce more alert mentality; relieve troubles which resisted other treatments; that the article was unsurpassed as a nerve tonic and for inducing refreshing sleep and a wonderful peace of mind; to invigorate the whole body; prevent various ailments and bodily complaints; improve circulation; show up dead spots in the body; and that it was a universal healer which would maintain good health in the user; cause vegetable growth to be twice as rapid as before; and that "God's Life Force" is in it; 502(b)(1)—the device failed to bear a label containing the name and address of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling failed to bear adequate directions for use for the above-described conditions and purposes, and adequate directions for such use could not be prepared, since the article was worthless for any treatment or therapeutic purposes.

DISPOSITION: 3–23–65. Default—50 devices and all of the pamphlets delivered to Food and Drug Administration and remainder destroyed.

8587. Vapozone device. (F.D.C. No. 50588. S. No. 65–013 A.)

QUANTITY: 18 devices at Hollywood, Calif.

SHIPPED: Between 2–18–63 and 7–23–64, from Detroit, Mich., by Vapozone Corp.

LABEL IN PART: (Device) "Made in Switzerland Type 7 * * * C. Ronzi, Zurich Suisse."

ACCOMPANYING LABELING: Leaflet entitled "Ophthalmological International Journal of Ophthalmology"; pieces of promotional literature reading in part "Vapozone for Beauty & Health," "Instructions for Operating Vapozone Machine," and "Instructions for Treatment of the Hair with the Vapozone Apparatus"; and reprint from the September issue of Harper's Bazaar of article entitled "Beauty Bazaar."

RESULTS OF INVESTIGATION: The inspector's photographs, and the literature, indicated the device to be a steam and high-frequency generator. The steam generator consisted of a water reservoir and a steam receptacle where mechanical arrangements had been made so that only as much water was received as was barely necessary for generating a desired amount of steam. A high-tension generator had been built into the same container as the steam generator, and was activated by means of a switch on the case. The steam thus generated was fed through a flexible pipe into a nozzle which was adjustable by means of a manual device to point in any selected direction. This manual device also controlled a high-frequency electrical field in such manner that the steam, as well as the air automatically drawn in by means of injector effect (or, instead of air, pure oxygen), must pass through the discharge of this high-frequency field. In use, the device was intended to emit steam, oxygen, ozone, hydrogen peroxide, and ions.

LIBELED: 9–28–64, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the devices were adequate and effective as a treatment of gaseous gangrene, eye diseases, acne vulgaris, wounds and infected wounds, damaged and infected tissue, infantile paralysis and different rheumatic complaints, herpes cornea simplex, herpes cornea simplex rezidivis, Beratitis mettaherpetica, traumatic alterations of the cornea with rising ulcus serpens, rezidiv erosions, and alteration of the cornea not traumatic and without herpes, eye inflammation, conjunctivitis sicca, pulpitis, paradentosis, dental granuloma, infections at the roots of the teeth, badly healing wounds, all wounds with aseptic and septic necrosis or gangrene, and extensive bed sores, and that use of the devices had a regenerating effect on skin and left the skin in a far healthier condition, that one of the results of their use was regeneration of the hair, that their use opened the pores of the skin without damaging even the tenderest tissue, that they were amazingly effective in stimulating new cell growth and enriching the blood circulation, that they fed nutrients to the hair and scalp and prevented the recurrence of dandruff, also disinfected wounds and neutralized toxins, favorably influenced the protoplasm, stimulated the reticuloendothelial system, improved the formation of granulation at places of trophic disturbances, for altering the whole organism, improving the whole digestive process and circulation, effectively resisted infections, deprived toxins of their poisons, or at least greatly reduced their effects, stopped the process of decomposition in necrotic tissue, stimulated phagocytosis or leukocytosis, accelerated mitosis and new cell building, for mobilizing natural healing and defense forces in a weakened body, increased the metabolism within the tissues and had a very definite bactericidal effect without any harm to the tissues, and for restoring the whole organism; and 502(f)(1)—the labeling of the devices failed to bear adequate directions for use for the treatment of the above-listed conditions or for effecting the above purposes.

DISPOSITION: On 1–18–65, Vapozone Corp., Detroit, Mich., claimed the devices; and, on 1–20–65, a consent decree of condemnation was entered which provided for salvaging the article under bond. On 3–15–65, such bond not having been filed, the Government moved to vacate the consent decree and for entry of default. On 3–29–65, the matter came on for hearing in court and the claimant failed to appear. On 3–31–65, the consent decree was vacated, a default was entered against the claimant, and a default decree was filed. The default decree ordered that 2 devices and 2 pamphlets be delivered to the Food and Drug Administration and that the remainer of the devices and pamphlets be destroyed.

8588. **Rainbow-Rexair vacuum cleaner.** (F.D.C. No. 51112. S. No. 19–276 B.)

QUANTITY: 9 devices, at San Francisco, Calif., in possession of Golden State Enterprises.

SHIPPED: Between 12–22–64 and 1–29–65, and unknown dates, from Syracuse, N.Y.

LIBELED: 3–12–65, N. Dist. Calif.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for bad colds, coughing, sneezing, flu, sinus conditions or any congestion you may have had in your nostrils or any place, asthma, hay fever, lung cancer, strep throat, and low resistance; and that use of the article would prevent death from polluted air, completely clear the nasal passages,

and remove all dust from a room; which were the conditions and purposes for which the article was offered in oral statements made by Mrs. Joan Canale, a sales representative for Golden State Enterprises, during the course of a demonstration given on 2–9–65.

DISPOSITION: 4–21–65. Default—delivered to the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF INSANITARY CONDITIONS

8589. Whole human blood. (F.D.C. No. 47087. S. No. 39–919 T.)

INDICTMENT RETURNED: 1–25–62, S. Dist, N.Y., against Westchester Blood Service, Inc., and John P. Calise, of New Rochelle, N.Y.

ALLEGED VIOLATIONS: Between the approximate dates of 2–28–60, and 6–29–61, the Westchester Blood Service, Inc., with intent to defraud and mislead, caused to be introduced into interstate commerce for shipment from New York to New Jersey, Massachusetts, and Puerto Rico, quantities of *whole human blood* which were misbranded under 502(a).

The indictment alleged also that while quantities of *whole human blood* were being held for sale in the State of New York after shipment in interstate commerce, the Westchester Blood Service, Inc., did, between 10–14–60 and 8–11–61, in the case of 22 separate lots of such blood, and John P. Calise, did, between 10–17–60 and 5–31–61, in the case of 3 separate lots of such blood, cause to be altered, mutilated, destroyed, obliterated and removed, with intent to defraud and mislead, the original expiration date on the labeling of such blood and caused the labeling to show a different and later expiration date with the result that the blood was misbranded.

The indictment alleged further that the defendants conspired, among other things, to violate the Federal Food, Drug, and Cosmetic Act, and that it was a part of the conspiracy that the defendants (1) would cause to be introduced into interstate commerce, with intent to defraud and mislead, *whole human blood* which was misbranded under 502(a), (2) would, with respect to *whole human blood*, while being held for sale after shipment in interstate commerce and with intent to defraud and mislead, alter, mutilate, destroy, obliterate and remove the labeling of the blood by changing the expiration date thereon to a later date with the result that the blood would be misbranded, (3) would cause to be introduced into interstate commerce, *whole human blood* and products derived therefrom which were adulterated under 501(a)(2)(A), (4) would cause to be introduced into interstate commerce, *whole human blood* in plastic bags and washed cells therefrom which were misbranded under 502(a), and (5) that the defendants would adulterate and misbrand in interstate commerce, within the meaning of 501(a)(2)(A) and 502(a), *whole human blood* and products derived therefrom.

It was alleged further that, in furtherance of the conspiracy and to effect the objects thereof, the defendants committed a number of overt acts consisting of shipping blood to various hospitals on 5–25–60, 12–27–60, 3–7–61, 5–5–61, and 5–31–61.

CHARGE: 501(a)(2)(A)—*whole human blood* and products derived therefrom were prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health, in that blood was transferred from one container to another after drawing, and washed cells were prepared without proper safeguards; and 502(a)—the labeling of the blood and products derived therefrom was false and misleading with respect to the name

of the manufacturer, and such labeling was false and misleading also with respect to the expiration date thereon, in that the original labeling of the blood and the products derived therefrom had been changed to show a later date than that which had been affixed originally.

DISPOSITION: The defendants filed a motion for dismissal of the indictment and, on 8–14–62, the court handed down an opinion in which it denied such motion (217 F. Supp. 705). Thereafter, the defendants entered pleas of guilty and, on 6–3–64, the court, with respect to the charges involving violations of the Federal Food, Drug, and Cosmetic Act, fined the corporation $1,550; sentenced the individual to 1 year in jail, which sentence was suspended; and placed the individual on probation for 5 years.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

8590. **Cof-Quel syrup.** (F.D.C. No. 51149. S. Nos. 15–094 B, 15–097 B.)

QUANTITY: 200 16-fl.-oz. btls. at Los Angeles, Calif.

SHIPPED: 12–3–64 and 12–7–64, from Long Island City, N.Y.

LIBELED: 3–17–65, S. Dist. Calif.

CHARGE: 501(a)(1)—while held for sale, the article contained mold.

DISPOSITION: 4–9–65. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

8591. **Chorionic gonadotropin.** (F.D.C. No. 51406. S. No. 38–688 B.)

QUANTITY: 1 shipping ctn. containing 302 unlabeled vials, at Oradell, N.J.

SHIPPED: 3–10–65, from Chicago, Ill. This was a return shipment.

LABEL IN PART: (Ctn.) "Distributed by Dell Laboratories * * * Teaneck, N.J. * * * Chorionic Gonadotropin 5,000 IU/vial * * * For manufacturing * * * Caution: Federal law prohibits."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 10 percent of the declared potency.

LIBELED: 6–3–65, Dist. N.J.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 IU/vial" was false and misleading.

DISPOSITION: 7–23–65. Default—destruction.

8592. **Methrol capsules.** (F.D.C. No. 51282. S. No. 33–673 B.)

QUANTITY: 1 ctn. containing approximately 36,697 capsules, at Battle Creek, Mich.

SHIPPED: 11–20–64, from Orange, N.J., by Ryson Laboratories, Inc.

LABEL IN PART: (Ctn.) "Methrol-Caps * * * Lot No. 1634 * * * 48,100 Amount * * * Methrol Capsule T.D.C. * * * Each Capsule Contains: Dienestrol 0.25 mg. Methyltestosterone 5.0 mg. Caution: * * * Ryson Laboratories, Inc., 116 Main Street, Orange, New Jersey."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 81.2 percent of the declared amount of methyltestosterone.

*See also Nos. 8566, 8569, 8571.

LIBELED: 4–26–65, W. Dist. Mich.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Each Capsule Contains: * * * Methyltestosterone 5.0 mg." was false and misleading.

DISPOSITION: 6–28–65. Default—destruction.

8593. **Pentrate-2 and Pentrate-3 tablets.** (F.D.C. No. 51383. S. Nos. 25–834 B, 26–207 B.)

QUANTITY: 1 4,000-tablet btl. and 4 1,000-tablet btls., of *Pentrate-2*, and 21 1,000-tablet btls. and 5 5,000-tablet btls., of *Pentrate-3*, at St. Louis, Mo., in possession of Manola Pharmacal.

SHIPPED: 12–31–62 and 8–14–62, from Indianapolis, Ind., and Chicago, Ill.

LABEL IN PART: (Btl.) "Pentrate-2 Penta-Erythritol Tetranitrate with Phenobarbital Each tablet contains: Penta-erythritol Tetranitrate 10 mgm. Phenobarbital ¼ gr. Warning * * * Distributed by Physicians Supply St. Louis, Missouri. Average Dose: * * * Caution: Federal law prohibits," and "Pentrate-3 Pentaerythritol Tetranitrate Each tablet contains: Penta-erythritol Tetranitrate 20 mg. Sole Distributor Bush Laboratories St. Louis, Missouri Average Dose: * * * Caution."

RESULTS OF INVESTIGATION: The article, *Pentrate-2*, was manufactured by the dealer in part from phenobarbital, which was shipped in bulk lot from Chicago, Ill., and both of the articles were manufactured by the dealer in part from pentaerythritol tetranitrate, which was shipped in bulk lot from Indianapolis, Ind.

Analysis showed that the article, *Pentrate-2*, contained approximately 145 percent of the declared amount of both phenobarbital and pentaerythritol tetranitrate, and that the article, *Pentrate-3*, contained approximately 66 percent of the declared amount of pentaerythritol tetranitrate.

LIBELED: 5–14–65, E. Dist. Mo.

CHARGE: 501(c)—while held for sale, the strength of the articles differed from that which they were purported to possess; and 502(a)—the label statements, *Pentrate-2*, "Each tablet contains: Penta-Erythritol Tetranitrate 10 mgm. Phenobarbital ¼ gr.," and *Pentrate-3*, "Each tablet contains: Pentaerythritol Tetranitrate 20 mg.," were false and misleading as applied to products containing more (*Pentrate-2*) and less (*Pentrate-3*) than the declared amounts of these ingredients.

DISPOSITION: 7–2–65. Default—destruction.

8594. **Menadione sodium bisulfite injection.** (F.D.C. No. 51303. S. No. 51–990 B.)

QUANTITY: 115 boxes, each containing 100 ampuls, at Philadelphia, Pa., in possession of Harvey Laboratories, Inc.

SHIPPED: On 3–25–60 and 11–13–62, from Chicago, Ill., and New York, N.Y.

LABEL IN PART: (Box) "1 ml. * * * Menadione Sodium Bisulfite Injection USP (Vitamin K) Menadione Sodium Bisulfite 10 mg. Sodium Chloride 9 mg. * * * Use * * * Dose * * * Toxicity * * * Caution * * * Harvey Laboratories Philadelphia 44, Pa."

RESULTS OF INVESTIGATION: The article had been manufactured by the dealer in part from menadione and sodium chloride which had been shipped as described above.

Analysis showed that the article contained approximately 70 percent of the declared amount of menadione sodium bisulfite. The United States Pharmacopeia required 90 to 110 percent of the declared amount.

LIBELED: 5-10-65, E. Dist. Pa.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, "*Menadione Sodium Bisulfite Injection*," the name of which was recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Menadione Sodium Bisulfite 10 mg." was false and misleading.

DISPOSITION: 6-9-65. Default—destruction.

8595. Cold capsules (2 seizure actions). (F.D.C. Nos. 51250; 51251. S. Nos. 33-604 B; 53-863 A.)

QUANTITY: 576 18-capsule btls., at Allegan, Mich.; and 420 18-capsule btls., at Detroit, Mich.

SHIPPED: 5-31-63, from Milwaukee, Wis.

RESULTS OF INVESTIGATION: The article was shipped in bulk, as above described, to Allegan, Mich., where it was repacked into the 18-capsule bottles, and then shipped in part to Detroit, Mich.

Analysis showed that the article contained approximately 58 percent of the declared amount of aspirin. The article contained free salicylic acid, presumably from decomposition of a portion of the aspirin present in the article at the time of manufacture.

LIBELED: 4-5-65, W. Dist. Mich.; and 5-13-65, E. Dist. Mich.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it was purported to possess.

DISPOSITION: 5-7-65 and 7-26-65. Default—destruction.

8596. Antacid tablets. (F.D.C. No. 51071. S. Nos. 10-969 A, 10-623 A.)

QUANTITY: 63 drums, each containing approximately 12,025 tablets, at Capitol Heights, Md.

SHIPPED: 11-14-62, from Yonkers, N.Y., by Bard Pharmaceuticals, Inc.

LABEL IN PART: (Drum) "Special Formula Department Date 11-8-62 Lot No. H62-2619 Quantity 12,025 Formula No. Antacid Tablets Cherry Flavor * * * For Relief of Gastric Hyperacidity Each Tablet Contains: Calcium Carbonate 842.4 mg. Ascorbic Acid (as Calcium Ascorbate) 50 mg. * * * Manufactured for Burton, Parsons Company * * * by Bard Pharmaceuticals Inc. * * * Yonkers, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article failed to contain vitamin C (ascorbic acid) as declared on the label.

LIBELED: 2-9-65, Dist. Md.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Ascorbic Acid * * * 50 mg." was false and misleading.

DISPOSITION: 4-30-65. Default—destruction.

8597. Prolens wetting solution. (F.D.C. No. 51155. S. No. 15–338 B.)

QUANTITY: 125 btls. at North Hollywood, Calif.

SHIPPED: 12–18–64, from Brooklyn, N.Y., by Sterimed, Inc.

LABEL IN PART: "Prolens Wetting Solution for Plastic Contact Lenses 60 cc Sterile Sterimed, Inc. * * * Brooklyn 7, N.Y."

LIBELED: 4–2–65, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality fell below that which it was purported to possess; and 502(a)—the label statement "Prolens Wetting Solution" was false and misleading as applied to a product which was semisolid or gelled as a result of physical or chemical change.

DISPOSITION: 4–30–65. Default—destruction.

8598. Retraction cotton (dental). (F.D.C. No. 51513. S. No. 17–877 B.)

QUANTITY: 324 ctns., each containing 12 individually pkgd. plastic btls., at Camarillo, Calif., in possession of Belport Co., Inc.

SHIPPED: 3–11–65, from Bothell, Wash.

LABEL IN PART: (Ctn.) "Retraction Cotton"; (pkg. & btl.) "Gingi-Pak (R) by Orostat Retraction Cotton * * * Contains a long staple cotton sliver impregnated with a specially prepared racemic epinephrine hydrochloride, approximately 1 mg. per inch Caution * * * Federal Law Prohibits * * * Distributed by Surgident, Ltd., Los Angeles 66, Calif."; and (pkg. insert) "Gingi-Pak Pellets * * * Gingi-Pak Retraction Technique * * * A note of caution."

RESULTS OF INVESTIGATION: The article was manufactured by Belport Co., Inc., by impregnating cotton with epinephrine which had been shipped in bulk lots from the State of Washington. Belport Co., Inc., subsequently packed the article into the containers described above and shipped it to the dealer in Los Angeles, Calif., who thereafter returned the article to Belport Co., Inc.

Examination showed that the article contained approximately 653 percent of the declared amount of epinephrine.

LIBELED: 7–13–65, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Contains * * * racemic epinephrine hydrochloride, approximately 1 mg. per inch" was false and misleading.

DISPOSITION: 8–5–65. Default—destruction.

8599. Rubber prophylactics. (F.D.C. No. 51396. S. No. 38–179 B.)

QUANTITY: 10 cases, each containing 4 6-pkg. ctns. of 12 individually foil-wrapped rubber prophylactics, at New York, N.Y.

SHIPPED: 3–31–65, from Akron, Ohio, by Killashun Sales Div. of Akwell Corp.

LABEL IN PART: (Pkg. of 12) "Contents * * * Nipple End Sultan Lubricated Prophylactics * * * Assists in Protecting Health Through The Prevention of Venereal Disease and the Reinfection of the Female With Trichomonas Sold For The Prevention of Disease Only * * * Mfd. by The Akwell Corp., Akron, Ohio," and (ctn.) "One Half Gross Nipple End Sultan Lubricated Prophylactics Mfd. by The Akwell Corp."

RESULTS OF INVESTIGATION: Examination of 288 prophylactics showed that 1.7 percent were defective in that they contained holes.

LIBELED: 5–21–65, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements "Assists in Protecting Health Through The Prevention of Venereal Disease and the Reinfection of the Female With Trichomonas" and "Sold For The Prevention of Disease Only" were false and misleading as applied to a product containing holes.

DISPOSITION: 6–30–65. Default—destruction.

8600. Rubber prophylactics. (F.D.C. No. 51407. S. No. 17–771 B.)

QUANTITY: 65 ctns., each containing 6 pkgs. of 4 3-unit boxes, at Phoenix, Ariz.

SHIPPED: 3–29–65, from Dallas, Tex., by McDonald Distributing Co., Inc.

LABEL IN PART: (Pkg.) "Contents * * * Nipple End Sultan Lubricated Prophylactics * * * Mfd. by The Akwell Corp., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that approximately 1.5 percent of the units were defective in that they contained holes.

LIBELED: 6–10–65, Dist. Ariz.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements (package) "Assists in protecting health through the prevention of venereal disease and the reinfection of the female with trichomonas" and "Sold for the prevention of disease only" were false and misleading.

DISPOSITION: 7–21–65. Default—destruction.

8601. Rubber prophylactics. (F.D.C. No. 51256. S. Nos. 46–744 B, 46–746 B.)

QUANTITY: 47 ctns., each containing 48 vials of 3 *Regal prophylactics* each, and 39 ctns., each containing 72 2 individually foil-wrapped pkgs. of *Rx 707 prophylactics*, at Chicago, Ill.

SHIPPED: 2–16–65, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Ctn.) "One Gross Regal Prophylactics * * * Plastic Vials * * * Sold for the prevention of disease only * * * Manufactured by Circle Rubber Corp. Newark, N.J." (pkg.) "Rx 707 with Sensi-lube * * * Two Prophylactics * * * Manufactured by Circle Rubber Corp. Newark, N.J. Sold for the prevention of disease only," and (unit) "Genuine Latex * * * Sold for prevention of disease only."

RESULTS OF INVESTIGATION: Examination showed that 0.77 percent of the *Regal prophylactics* tested and 0.96 percent of the *Rx 707 prophylactics* tested were defective in that they contained holes.

LIBELED: 4–9–65, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they were purported to possess; and 502(a)—the label statement (cartons and units) "Sold for ["the"] prevention of disease only" was false and misleading as applied to products containing holes.

DISPOSITION: 5–24–65. Default—destruction.

DRUGS FOR VETERINARY USE

8602. **Rumi-Jex Polysaccharide complex injection.** (F.D.C. No. 51395. S. No. 26–256 A.)

QUANTITY: 40 ctns., each containing 12 100-cc. btls., and 100 100-cc. loose btls., at Chicago, Ill., in possession of William Cooper & Nephews, Inc.

SHIPPED: Between 4–19–62 and 5–31–62, from Des Moines, Iowa.

LABEL IN PART: (Btl. and ctn.) "Cooper * * * Rumi-Jex Polysaccharide Complex Injectable Iron* For Cattle With Vitamins B_1 and B_{12} Contains Equiv. 100 mg. Elemental Iron Per. cc. Manufactured for Wm. Cooper & Nephews, Inc. Chicago 14, Illinois * * * for treatment and prevention of iron deficiency anemia in cattle caused by parasitism, blood loss, poor nutrition and other debilitating conditions * * * Each 1 cc. contains * * * 15 mcg. Vitamin B_{12} U.S.P., 5 mg. Thiamine Mononitrate."

ACCOMPANYING LABELING: Display card entitled "New For Cattle * * * Cooper Rumi-Jex Injectable Iron with Vitamins B_1 and B_{12} Better Disease Resistance . . . Weight Gains . . . Feed Conversion At Less Cost," and insert in carton entitled "Rumi-Jex Polysaccharide Complex Injectable Iron* For Cattle With Vitamins B_1 and B_{12} For Livestock."

RESULTS OF INVESTIGATION: The bottles were shipped in bulk lots and were repacked by the dealer into the cartons described above, at which time the inserts and display cards were added.

Analysis showed that the article contained approximately 27.4 percent of the declared amount of thiamine mononitrate.

LIBELED: 5–19–65, N. Dist. Ill.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which is was purported to possess; and 502(a)—the label statement (bottle and carton) "Each 1 cc. contains * * * 5 mg. Thiamine Mononitrate (B_1 Mononitrate)" was false and misleading.

DISPOSITION: 7–6–65. Default—destruction.

8603. **Medicated poultry feed.** (F.D.C. No. 51102. S. No. 22–051 B.)

QUANTITY: 143 50-lb. bags, at Fort Worth, Tex., in possession of Nutrena Mills, Feed Div. of Cargill, Inc.

SHIPPED: 6–1–64, from Ashland, Ohio.

LABEL IN PART: (Bag) "Cargill Nutrena Complete Pullet Grower (S) Medicated Crumbilized * * * Active Drug Ingredient: Nihydrazone 15-nitro-2-furaldehyde acetylhydrazone 0.011% * * * Manufactured by Nutrena Mills, Division of Cargill, Incorporated * * * Minneapolis, Minn."

RESULTS OF INVESTIGATION: The medicated poultry feed was manufactured by Nutrena Mills, in part, from a drug ingredient, nihydrazone, which was shipped as described above. Analysis showed that the article contained approximately 51.8 to 58.8 percent of the declared amount of nihydrazone.

LIBELED: 3–18–65, N. Dist. Tex.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Nihydrazone * * * 0.011%," was false and misleading; and 502(a)—the labeling, namely, the bag label, contained false and misleading representations that the article was adequate and effective for the prevention and treatment

of chronic respiratory disease (Air-sac infection) to reduce mortality and severity of infection in chronic respiratory disease, maintain weight gains and feed efficiency, for the prevention of pullorum disease, fowl typhoid, paratyphoid (Salmonellosis), coccidiosis caused by *E. tenella*, *E. necatrix*, *E. maxima*, and *E. brunetti*, and histomoniasis (blackhead).

DISPOSITION: 5-11-65. Consent—claimed by Cargill, Inc., Minneapolis, Minn., and released to be brought into compliance with the law. The claimant having thereafter failed to bring the article into compliance, the court, on 8-4-65, ordered that the article be destroyed.

8604. Medicated poultry feed. (F.D.C. No. 51148. S. No. 52-012 B.)

QUANTITY: 44 100-lb. bags at Tunkhannock, Pa.

SHIPPED: 12-7-64, from Buffalo, N.Y., by Agway, Inc.

LABEL IN PART: (Tag on bag) "G-1 Agway Medicated Commander unscreened crumbles (Red tag chick starter) 1661917BF for treatment of outbreaks of coccidiosis in poultry flocks * * * Active drug ingredient: sulfaquinoxaline 0.05% * * * Agway, Inc., Syracuse, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 74 percent of the declared amount of sulfaquinoxaline.

LIBELED: 3-16-65. M. Dist. Pa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "sulfaquinoxaline 0.05%" and the label statements which represented and suggested that the article was adequate and effective as a treatment for coccidiosis were false and misleading.

DISPOSITION: 5-25-65. Default—destruction.

8605. Medicated poultry feed. (F.D.C. No. 51262. S. No. 6-172 B.)

QUANTITY: 160 50-lb. bags, at Kansas City, Mo., in possession of Quisenberry Mills, Inc.

SHIPPED: 6-29-64, drug premix, from Ashland, Ohio.

LABEL IN PART: (Tag on bag) "Q-B Plus Starter (Chick Boost) Quickies Medicated Feed to chicks from one day of age until 7 weeks old. Do not feed to older chickens. * * * Follow feeding directions on back of tag Active Drug Ingredient: Nihydrazone (5-nitro-2-furaldehyde acetylhydrazone) 0.011% * * * Quisenberry Mills, Inc. Kansas City, Missouri."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of nihydrazone.

The article had been manufactured by the dealer in part from a drug premix which was shipped as described above.

LIBELED: 4-13-65, W. Dist. Mo.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement of the article "Nihydrazone * * * 0.011%" was false and misleading.

The libel alleged also that the article was adulterated under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

DISPOSITION: 6-14-65. Default—delivered to Municipal Farms, Kansas City, Mo., for use as poultry feed only.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

8606. Citrated whole blood (human). (F.D.C. No. 50619. S. No. 78–341 A.)

INDICTMENT RETURNED: 7–10–63, Dist. N.J., against Paterson Blood Bank, Inc., Stephen Lillo, and John Chiesa, of Paterson, N.J.

SHIPPED: Between 6–19–62 and 8–30–62, from Paterson, N.J., to Richmond, Staten Island, N.Y.

CHARGE: 502(a)—when shipped, the label of the article represented that the article was *citrated whole blood* (*human*) of negative reaction to a venereal disease research laboratory (VDRL) serological test for syphilis, which representation was false and misleading since the article was of positive reaction to a venereal disease research laboratory (VDRL) serological test for syphilis.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court on 5–6–64. On 6–3–64, Stephen Lillo and John Chiesa were acquitted and the Paterson Blood Bank, Inc., was found guilty on the charges of violating the Federal Food, Drug, and Cosmetic Act. On 6–12–64, the Paterson Blood Bank, Inc., was fined $1,500 with respect to such charges.

8607. Various drugs. (F.D.C. No. 46188. S. Nos. 97–701/5 R, 97–708/10 R.)

QUANTITY: 283 1-oz. btls. of *Streptomagna*, 213 ½-oz. btls. of *Bicillin Sulfas*, 69 btls. of *Pen-Vee Sulfas*, 21 tubes of *Caldecort Dermatologic Ointment*, and some 57 other articles of drug consisting of unknown quantities of prescription drugs, at Buffalo, N.Y., in possession of Niagara Drug Co.

SHIPPED: On unknown dates, from outside the State of New York.

LABEL IN PART: (Btls.) "Streptomagna * * * Sample: Not to be sold," "Bicillin Sulfas * * * Sample: Not to be sold," "Pen-Vee Sulfas * * * Sample: Not to be sold," and (tube) "Caldecort Dermatologic Ointment * * * Professional Sample"; and other labels bearing such words as "Professional Sample," "Complimentary," and "Not to be sold."

LIBELED: 7–28–61, W. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the words "Professional Sample," "Complimentary," "Not for Sale," or similar wording, were false and misleading as applied to these articles which were intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 4–15–65. Default—destruction.

8608. Nutricol capsules. (F.D.C. No. 50987. S. No. 83–846 A.)

QUANTITY: 693 90-capsule btls., at Bronx, N.Y., in possession of Nutrition Control Products.

SHIPPED: 12–11–63, from Detroit, Mich.

LABEL IN PART: (Btl.) "Nutricol Lipotropic Factors with Unsaturated Fatty Acids Nutrition Control Products New York, N.Y. Sole Dist. Suggested Dose: As a supplementary source of lipotropic factors and unsaturated fatty acids, three capsules daily."

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*See also Nos. 8562–8564, 8566, 8568, 8570, 8579–8581, 8583, 8585–8587, 8589, 8591–8594, 8596–8601.

ACCOMPANYING LABELING: File cards entitled "Nutricol* Capsules For Hypercholesterolemia," and catalogs entitled "N.C.P. Formulary and Therapeutic Guide."

RESULTS OF INVESTIGATION: The dealer repacked the article into the bottles and also prepared the file cards and catalogs.

LIBELED: On or about 2–24–65, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the prevention, treatment, and cure of lipid abnormalities, including hyperlipemia, xanthelasma, nephrosis, sprue, steatorrhea, celiac disease, and faulty fat metabolism; hypercholesterolemia, such as conditions associated with abnormal cholesterol metabolism, including coronary heart disease (angina pectoris, postmyocardial infarction), atherosclerosis (general and cerebral), xanthomatosis, nephrosis, peripheral vascular disorders, strokes, hypertension, and postmenopausal state; conditions affecting the eyes, including senile macular degeneration, diabetic, hypertensive and arteriosclerotic retinopathies, vitreous opacities, choroiditis, diabetes mellitus, poor visual acuity, and keratosis; liver disorders, including alcoholism, cirrhosis, fat intolerance, fatty liver, and hepatitis; skin disorders due to faulty lipid metabolism as in psoriasis, nummulare eczema, keratosis, seborrhea, and certain dry skin conditions; diseases of infants, including celiac disease, certain eczemas, abnormal aciduric intestinal flora; and other disease conditions, including diabetes mellitus, obesity, geriatric conditions, rheumatoid arthritis, certain allergic states, constipation, and pruritus ani (by promoting an aciduric intestinal flora).

DISPOSITION: 4–5–65. Default—destruction.

8609. Histac cold capsules. (F.D.C. No. 50099. S. No. 18–381 A.)

QUANTITY: 6 bulk cases, each containing 1,200 12-capsule strips; 1 case, containing 1,088 12-capsule strips; and 33 repacked sleeve-type containers, each containing 12 unlabeled 12-capsule strips; and unknown quantities of sleeve-type containers and display ctns., at Verona, Pa., in possession of Pennex Products Co., Inc.

SHIPPED: 12–30–63, from Hempstead, L.I., N.Y.

LABEL IN PART: (Sleeve) "Antihistamine Decongestant Histac Sustained Action Capsules for continuous relief of nasal congestion due to colds and hay fever * * * Day and Night Relief * * * Decongests stuffed-up nose/Helps drain nasal passages/Relieves itchy, watery eyes * * * Each Timed Disintegration Capsule Contains: Belladonna Alkaloid Salts 0.16 mgm. consisting of Atropine Sulfate 0.024 mgm. Scopolamine Hydrobromide 0.014 mgm. Hyoscyamine Sulfate 0.122 mgm. Phenylpropanolamine Hydrochloride 50 mgm. Chlorpheniramine Maleate 1 mgm. Pheniramine Maleate 12.5 mgm. Caution * * * Distributed by Pennex Products Co., Pittsburgh, Pa.," and (display ctn.) "Antihistamine Decongestant Histac For Colds Hay Fever."

RESULTS OF INVESTIGATION: The article of drug was shipped in bulk cases and was repacked and relabeled by the dealer into the sleeve-type containers described above.

LIBELED: 5–4–64, W. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling of the article, namely, the cardboard sleeve and the display cartons described above, contained false and misleading representations that a single *Histac cold capsule* containing the

amounts of ingredients declared in the label would provide 12 hours of continuous relief of excessive nasal discharge, running nose, itchy, watery eyes, nasal congestion, stuffy, congested feeling and other conditions caused by the common cold and hay fever.

DISPOSITION: On 6–10–64, Pennex Products Co., Inc., claimant, filed an answer to the libel denying that the article was misbranded. On 12–28–64, interrogatories were served upon the claimant. On 5–6–65, the claimant having failed to answer the interrogatories, a decree of condemnation and destruction was entered.

8610. Lix-Pain liniment. (F.D.C. No. 51007. S. No. 111–068 A.)

QUANTITY: 7 cases, each containing 15 6-fl.-oz. btls., at Pittsburg, Kans.

SHIPPED: 8–21–64, from Kinston, N.C., by Oglesby Chemical Co.

LABEL IN PART: (Btl.) "Lix-Pain Cream Liniment * * * Active Ingredients: Ammonium Carbonate, Camphor, Turpentine, Thyme Lanolin. Caution: Use only as directed * * * Distributed by DeNeve's Chemical Co. Pittsburg, Kansas."

LIBELED: On or about 2–9–65, Dist. Kans.

CHARGE: 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective for the relief of rheumatic pains, swollen glands, arthritis, sinus, neuralgia, backache, headache, bruises and sprains.

DISPOSITION: 4–6–65. Default—destruction.

8611. Soberettes (2 seizure actions). (F.D.C. Nos. 50949/50. S. Nos. 49–177 A, 34–549 B.)

QUANTITY: 161 boxes, each containing 50 cellophane packets, at Detroit, Mich.

SHIPPED: 10–9–63 and 10–16–63, from San Antonio, Tex., by Universal Pharmaceutical Co.

LABEL IN PART: (Box) "Soberettes for overindulgence in food and drink * * * Universal Pharmaceutical Co. 827 W. Hildebrand San Antonio, Texas," and (packet) "Each chocolate capsule contains * * * Each white tablet contains * * * Each orange tablet contains * * * Soberettes Dosage: Entire Contents * * * Distributed by Universal Pharmaceutical Co. * * * San Antonio, Texas."

LIBELED: 2–15–65, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the name of the article, "*Soberettes*," and statements in its labeling (box) represented and suggested that the article was adequate and effective to make an intoxicated person sober, which name and statements were false and misleading, since the article was not adequate and effective for such purpose.

DISPOSITION: 5–3–65. Default—destruction.

8612. Les-Wate capsules. (F.D.C. No. 51086. S. No. 54–622 B.)

QUANTITY: 1 drum, containing approximately 12,400 capsules, and an undetermined number of repacked bottles, at Baltimore, Md., in possession of Reyman Drug Co., Inc.

SHIPPED: 1–7–65, from Brooklyn, N.Y.

LABEL IN PART: (Btl.) "Les-Wate Capsule-A-Day The Safe Effective Way Reyman Drug Co. Baltimore, Md. Distributors * * * Average Adult Dose:

One capsule on arising. Each capsule contains: Phenylpropanolamine HCL 50 mg. Released gradually and equivalent to 3 doses over a period of approximately 8 hours. As an oral decongestant."

ACCOMPANYING LABELING: Display cartons, reading in part, "Les-Wate Capsule-A-Day The Safe Effective Way."

RESULTS OF INVESTIGATION: In the ordinary course of the business operations of the dealer, Reyman Drug Co., Inc., the article in the drum was to be repacked into bottles labeled as described above.

LIBELED: 2–18–65, Dist. Md.

CHARGE: 502(a)—while held for sale, the name of the repacked article, "*Les-Wate*" the label statement (repack bottle label and display carton) "Capsule-A-Day" and "The Safe Effective Way," and the graphic representation of a slim, human female figure on the label (display carton), were false and misleading in that they represented and suggested that use of one capsule a day was adequate and effective to cause the user to lose weight, and that the user could reduce safely and effectively, whereas such representations and suggestions were contrary to fact.

DISPOSITION: 4–2–65. Default—destruction.

8613. Sauna bath device. (F.D.C. No. 50970. S. No. 78–921 A.)

QUANTITY: 43 individually ctnd. devices, at Edison, N.J., in possession of Cascade Sauna Corp.

SHIPPED: Between 6–10–64 and 11–2–64, from San Francisco, Calif., by Viking Sauna Corp.

LABEL IN PART: (Ctn.) "Viking Sauna * * * Producer A. B. Bahco Sweden Distributor Viking Sauna Corp. * * * San Francisco"; (metal plate on some devices) "Viking Sauna Corporation, San Francisco, California Model BTH 6 * * * Manufactured by the Ventilation Division Bahco, Enkoping, Sweden"; and (metal plate on some devices) "Sauna Heater Type BTD 9 * * * A. B. Bahco Ventilation Division Enkoping, Made in Sweden Distributed in USA by Viking Sauna Corp., San Francisco."

ACCOMPANYING LABELING: Books entitled "Sauna The Finnish Bath," "An Invitation * * * Viking Sauna," and "Installation Instructions for Cascade Sauna"; brochures entitled "Viking Sauna, a centuries old Scandinavian Institution," "Viking Sauna * * * The Modern Method of Relaxation," "Viking Sauna * * * and Leave Fatigue Behind," "AIA File No. 29–N–3 Viking Sauna," and "For healthful relaxation, The Finnish Sauna"; reprint testimonial letters, dated 6–28–63, from J. DeWitt Fox, M.D., Editor of Life and Health, The National Health Journal, and 1–7–63, from Robert E. Martens, A.I.A.; reprints entitled "California Builder * * * January 1962," "The Sauna * * * House Beautiful August 1961 Issue," and "News * * * Fact Sheet on Viking Sauna BTD–9"; reprints from Life Magazine dated 1–18–63; specification sheet for Viking Sauna; sheet entitled "Retail Price List"; and self-mailer entitled "Can you spare two hours a week to feel more alive again?"

RESULTS OF INVESTIGATION: Examination indicated that the article was an electric heater with a thermostat, for use in heating sauna bath enclosures. Some of the accompanying labeling had been shipped by the shipper and some had been prepared by the dealer. The accompanying labeling related to the device and was intended for promoting sales of the article.

LIBELED: 1–7–65, Dist. N.J.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying label contained false and misleading representations that the article was adequate and effective as a treatment for all viral diseases, including cancer; for relieving tensions; imparting vim, vigor, and vitality; smoothing and toning the skin; giving the muscles and body a good workout while sitting down, forcing complete relaxation; reducing body weight; insomnia; arthritis; hypertension; muscular ailments; common colds; acne; psoriasis; blemishes; sinus and bronchial problems; muscular and circulatory problems; prevention of viral diseases; better circulation throughout the body; hangovers; post-operative treatment; and to eliminate blood clots and post-operative infection; and that the article functioned as a drugless tranquilizer; gave you a complexion like a baby's; toned up muscles; eased the nerves; mobilized white blood cells, antibodies, and other immune agents against any bacteria or virus in the bloodstream or body cells; speeded up body processes; articulated joints whose functions had been impaired or lost; improved the function of the skin and eliminated the cause of offensive body odor; provided an inner house-cleaning and was a true inner catharsis; thinned the viscosity of the blood by 3 percent for every degree of temperature rise; and was a remedy for pain and sickness.

DISPOSITION: 2–11–65. Consent—claimed by Cascade Sauna Corp., Edison N.J., for relabeling. The accompanying labeling was destroyed and there was affixed to each device, the following sticker label: "WARNING—Elderly Persons Or Those Suffering From High Blood Pressure Should Not Use This Device Unless Directed By a Physician."

8614. Sylvan sauna device. (F.D.C. No. 50711. S. No. 90–023 A.)

QUANTITY: 3 devices, at Doylestown, Pa., in possession of Sylvan Pools, Inc.

SHIPPED: 6–25–64, from Camden, N.J.

LABEL IN PART: (Paper sign attached to device) "Sylvan Pools Is Proud to Announce Sylvan Sauna."

ACCOMPANYING LABELING: Folders entitled "Ponce de Leon Would Have Stayed in Spain"; undetermined quantities of loose pages to be inserted into the folders, entitled "The Powerhouse," "The House that Kenneth Built," "The Incomparable Benefits and Significance of Sauna," "Urethane Panel Insulation," and "Guarantee"; and catalogues entitled "Sylvan Pools 1964 Catalogue."

RESULTS OF INVESTIGATION: The device was an electrically heated, insulated, redwood chamber, approximately 5′ x 5′ or 5′ x 8′ and 75″ high, with a thermostat and a door to permit entrance of users for the purpose of exposing the body to alleged therapeutic benefits. Redwood benches were provided inside for sitting or reclining during the treatment.

The loose insert pages had been prepared by the dealer, and the folders and catalogues had been printed locally on the order of the dealer.

LIBELED: 11–17–64, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for respiratory infections; reducing and reshaping the anatomy; tension and high tension; blackheads; skin blemishes; rejuvenation; aches and pains; maintaining everyday health; morning-after hangovers; stimulating the appetite; and that use of the article produced keenness

of mind and better mental health, greater body health, and a body glowing with health; resistance to colds; beautiful and radiant complexions; revived one's constitution; promoted deep, natural sleep; a readiness for any challenge; established and maintained normal weight; deep-cleaned the skin; provided preventative medicine and speedy, more thorough elimination of body wastes and dead tissue; and that the article was a natural skin beauty treatment which greatly improved general body metabolism, cleansed the skin of deep-down dirt and dead tissue, substituted for hours of exercise, opened up pores, removed the causes of blackheads and skin blemishes, provided intense stimulation of the body and its processes, and gave inner cleansing, a more attractive body, and resulted in beautiful, peach-complexioned women and robust, vigorous men.

DISPOSITION: 2–2–65. Consent—claimed by Sylvan Pools, Inc., and released under bond for relabeling.

8615. Life A-Sauna steam bath device. (F.D.C. No. 51114. S. No. 54–538 B.)

QUANTITY: 3 unlabeled devices at Norfolk, Va.

SHIPPED: On an unknown date, from Waldorf, Md., to Arlington, Va., and reshipped, on 1–25–65, by Life A-Sauna, Div. of Area Associates, Inc., from Arlington to Norfolk, Va.

ACCOMPANYING LABELING: Brochures entitled "Life A-Sauna Your Personal Steam Bath * * * A Division of Area Associates, Inc.," which were shipped on 1–25–65, by Life A-Sauna, Div. of Area Associates, Inc.

RESULTS OF INVESTIGATION: Examination of the inspector's photographs and literature showed the device to be a fiber glass cabinet approximately 48" high, 33" deep, and 24" wide, weighing about 55 pounds, with a door opening both inward and outward. In use, the user sat on a stool inside the device and an electric steam generator produced steam through heating a container of water provided inside. The device was manufactured by Structure Fiberglass Co., Waldorf, Md.

LIBELED: 3–12–65, E. Dist. Va.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for daily tension, weight problem, to achieve and maintain normal weight, toning muscles, physical fitness, increase longevity, improve blood circulation, blackheads and skin blemishes, general fatigue, symptoms of respiratory infections, and mental fitness; and that, when using the device, expensive tranquilizers and other habit-forming tension relievers can be a thing of the past; that use of the article promoted health and a healthful radiant complexion, was a source of health and beauty and resulted in a tingling glow of health; and that it constituted a rejuvenation period for restoring mental and physical vigor; and 502(b)(1)—when shipped in interstate commerce, its label failed to bear the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 6–2–65. Default—destruction.

8616. McKune Whirlpool Bath device. (F.D.C. No. 51281. S. No. 48–920 B.)

QUANTITY: 11 devices (5 chrome and 6 turquoise enameled), at Pittsburgh, Pa., in possession of McKune Whirlpool of Western Pennsylvania.

SHIPPED: Between 1–22–65 and 3–8–65, from Chicago, Ill., by John J. McKune & Sons Co., Inc.

LABEL IN PART: (Chrome) "McKune Whirlpool Bath" and (turquoise) "Hydromassage Whirlpool Bath."

ACCOMPANYING LABELING: Leaflets entitled "What the Whirlpool Bath Unit is used for" and "Whirlpool Bath Unit"; framed posters entitled "Combats Nervous Tension," "Weight and Posture Control," "Tired Aching Feet—Poor Circulation," "Arthritis–Rheumatism–Aching Back," "Relax for Restful Sleep," and "Passive Stimulation"; unframed posters entitled "Your Own Health Spa At Home Relax and Get Fit," "Now Spot Whirlpool At Home," and "Strained Ligaments, Ankles, Sore Muscles, Bruises, Tired Feet, Legs, Fractures"; and tear sheets entitled "Relax And Get Fit" and "Gifts From LBJ."

RESULTS OF INVESTIGATION: Examination indicated the device to be an electric motor which forced air through a plastic tube attached to a perforated metal pipe, which pipe fitted into and around the bottom of a bathtub. The air which was forced through the perforated pipe agitated the water, causing it to become turbulent in order to effect an alleged therapeutic motion.

LIBELED: 4–23–65, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the printed promotional material described above, accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for poor circulation, arthritis and arthritic pain, rheumatism and rheumatic pain, aching back, nervous tension, sore feet and legs, and bursitis; for controlling body weight; controlling posture; toning muscles and body tissues; bruises; fractures; strained ligaments and strained ankles; and that use of the device produced quiet, restful sleep, passive exercise, and physical fitness for the entire body.

DISPOSITION: 6–16–65. Consent—claimed by Gordon C. Howard, t/a McKune Whirlpool of Western Pennsylvania, Pittsburgh, Pa., and released for relabeling.

8617. Vapozone device. (F.D.C. No. 51100. S. No. 34–971 B.)

QUANTITY: 2 devices, at Detroit, Mich., in possession of Kitty's Continental Skin-Care Salon.

SHIPPED: 1–8–64, from Zurich, Switzerland.

ACCOMPANYING LABELING: Booklet entitled "Kitty's Continental Skin-Care Salon."

RESULTS OF INVESTIGATION: The dealer had obtained the article from a local firm which had assembled it from parts shipped as above. The above booklet was intended for use by the dealer, in part, in the promotion of the article.

Examination indicated that the device consisted of a stream generator and a high-frequency generator. The former generator consisted of a water reservoir and a steam receptacle where mechanical arrangements had been made so that the electric radiator received only as much water as was barely necessary for generating a desired amount of steam. A high-tension generator had been built into the same container as the steam generator and was activated by means of a switch on the case. The steam thus generated was fed through a flexible pipe into a nozzle adjustable by means of a manual device to point in any selected direction. This manual device also controlled a high-frequency field in such manner that the steam, as well as the air automatically drawn in

by means of injector effect (or, instead of air, pure oxygen), must pass through the discharge of this high-frequency field. In use, the device was intended to emit steam, oxygen, ozone, hydrogen peroxide, and ions.

LIBELED: 3–9–65, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the booklet which accompanied the article contained false and misleading representations that the article was adequate and effective as a treatment for acne and severe cases of acne; wrinkles and wrinkled, leathery, or dry skin; greasy skin; enlarged pores; age spots; double chin; sagging jaw line; weak or sagging muscles; stubborn cases; poor blood circulation; scaliness or a crop of blemishes; and that the article was a revolutionary apparatus, the use of which rendered superassistance, preserving the youthful texture and elasticity of the skin much longer than nature was willing to allow, toning and firming the facial tissues, avoiding scarring from acne, and resulting in a clearer complexion.

DISPOSITION: On or about 3–26–65, Vapozone Corp., Detroit, Mich., filed an answer to the libel neither admitting nor denying the allegations of the libel. On 4–5–65, Kitty Wagner, t/a Kitty's Continental Skin-Care Salon, filed a claim to the article. On 6–30–65, the Vapozone Corp. withdrew its answer. On 9–23–65, Kitty Wagner, t/a Kitty's Continental Skin-Care Salon, consenting, the device seized was ordered released under bond to claimant for use only for cosmetic purposes; and the accompanying labeling was ordered destroyed, except for 2 booklets to be delivered to the Food and Drug Administration.

8618. Rest-A-Matic Mattress devices. (F.D.C. No. 51012. S. No. 11–858 A.)

QUANTITY: 14 devices at Harrisonburg, Va.

SHIPPED: On unknown dates, from York, Pa., by Amos M. Shertzer, t/a Rest-A-Matic of York.

LABEL IN PART: (Label on mattress) "Serta * * * Serta Mattress Co., Lancaster, Pa. Rest-A-Matic Helps You To Sleep And Relax * * * Distributed by L and M Sales Myerstown, Penna."

ACCOMPANYING LABELING: Leaflets entitled "Let Massage—Nature's Own Tranquilizer Help You Sleep and Relax Give Temporary Relief From Minor Muscular Aches Resulting From Fatigue" and "Rest-A-Matic Guarantee and Service Insurance Policy."

RESULTS OF INVESTIGATION: Examination indicated that each device was a full-size bed mattress with an electric motor mechanism inside which provided vibratory effect.

LIBELED: 2–12–65, W. Dist. Va.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for severe cases of arthritis, rheumatism, and similar ailments, tension, and cramps during difficult times of the month; and that its use had given amazing relief to many users suffering from many ailments; provided nature's own tranquilizer; produced healthful sleep and good health to the user; minimized swelling; would insure longer life; revitalized working nerves and muscles; kept user's bodies and minds firm and alert; would penetrate every fiber of the body and had a beneficial effect upon the order of life from the heart.

DISPOSITION: 3–29–65. Consent—claimed by L & M Enterprises, Myerstown, Pa., and relabeled.

8619. Walton's Belt Vibrator. (F.D.C. No. 51068. S. No. 29–884 B.)

QUANTITY: 21 devices, at Minneapolis, Minn., in possession of Abbey Rents.

SHIPPED: Between 5–1–64 and 12–16–64, from Dallas, Tex., by Walton Manufacturing Co.

ACCOMPANYING LABELING: Booklets entitled "Walton's Master Craft Belt Vibrator"; instruction sheets entitled "The Versatile EZE Massage Belt Vibrator with Added Pulse Action"; leaflets entitled "Walton . . . The finest Health Appliances for every need"; and newspaper advertisement mats reading in part "Be A Size 10 Again!"

RESULTS OF INVESTIGATION: Examination indicated the device to consist of a 4-inch-wide belt with leather ends attached to a housing containing a ¼-horsepower electric motor for producing vibrating effects. The device was supported at waist height on a single tubular support arising from a platform upon which the user stands.

Some of the accompanying labeling had been supplied by the shipper and some by the dealer firm.

LIBELED: 2–11–65, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the promotional material described above, accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for reducing weight, heavy thighs, and thick calves; stimulating circulation; tightening stomach muscles; strengthening muscles; cold or stiff hands; cramps; specialized figure control; and that use of the article before bedtime produced a wonderful night's rest; would trim you and slim you with deep penetrating massage for abdomen, hips, shoulders, chest, calves and thighs; make you feel better; streamline the body; bring quick relief to back, shoulders, and upper arms; concentrate massage on the layers of fatty tissues outside the stomach; result in intense massage for fatty portions of the body; and give the user increased health and vitality.

DISPOSITION: 3–29–65. Consent—claimed by Abbey Rents, Inc., Los Angeles, Calif., and Walton Manufacturing Co., Dallas, Tex., and relabeled; the literature was destroyed.

DRUG FOR VETERINARY USE*

8620. Medicated poultry feed. (F.D.C. No. 50980. S. No. 120–362 A.)

QUANTITY: 13 100-lb. bags, at Phoenix, Ariz., in possession of Arizona Milling Co.

SHIPPED: The ingredient, nihydrazone, was shipped on 6–2–64, from Ashland, Ohio.

LABEL IN PART: (Tag on bag) "Arizona Star Growing Ration Medicated—For the prevention of coccidiosis and for Growth Stimulation in Poultry. Active Drug Ingredients: Nitrofurazone .0055% Furazolidone .0008% * * * Ingredients * * * Manufactured by Arizona Milling Co. Phoenix."

RESULTS OF INVESTIGATION: The article was manufactured by Arizona Milling Co., in part, from the drug ingredient, nihydrazone. Analysis showed that the article contained nihydrazone and that it did not contain nitrofurazone or furazolidone.

LIBELED: 1–21–65, Dist. Ariz.

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*See also Nos. 8602–8605.

CHARGE: 502(a)—while held for sale, the label statement "Active Drug Ingredients: Nitrofurazone .0055% Furazolidone .0008%" was false and misleading.

The libel alleged also that the article was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–18–65. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 8561–8620

PRODUCTS

[1] (8564, 8565, 8572, 8579, 8609) Seizure contested.
[2] (8589, 8606) Prosecution contested.
[3] (8570) Seizure contested; injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[4] (8563) Injunction issued.

[5] (8568) Seizure contested. Motion for summary judgment; contains opinion of the court.

[1] (8564, 8565, 8572, 8579, 8609) Seizure contested.
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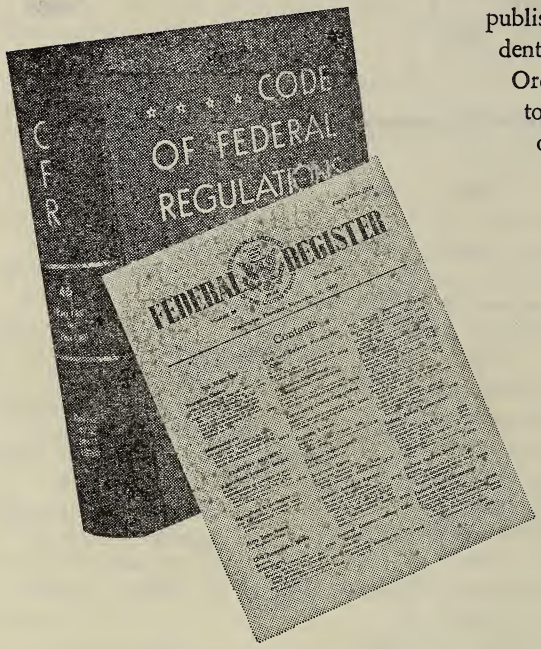

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D.D.N.J., F.D.C. 8621–8680 Issued December 1966

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

8621–8680

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *January 9, 1967.*

CONTENTS

239-423—67——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

8621. (F.D.C. No. 51060. S. Nos. 30–963/4 A.)

INFORMATION FILED: 6–9–65, S. Dist. Ohio, against **Frank Galilei, Columbus, Ohio.**

CHARGE: Between 8–6–64 and 8–11–64, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: On 9–29–65, the case came on for trial before the court without a jury and at the conclusion of the trial on the same day, the court found the defendant guilty. On 11–4–65, the court placed the defendant on probation for 5 years.

8622. (F.D.C. No. 51059. S. No. 30–965 A.)

INFORMATION FILED: 6–9–65, S. Dist. Ohio, against **George Curry, Columbus, Ohio.**

CHARGE: On 8–27–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–8–65. $200 fine, and probation for 3 years.

8623. (F.D.C. No. 51309. S. Nos. 50–822/3 A, 51–170 A, 51–884 A, 51–887/9 A, 51–892/3 A.)

INFORMATION FILED: 7–7–65, N. Dist. Ohio, against **Herman Drug Co. (a corporation), Cleveland, Ohio, Gerald P. Herman (vice president), and John D. Lohmier.**

CHARGE: Between 2–6–64 and 6–27–64, *amphetamine sulfate tablets* were dispensed 6 times, and *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Lohmier to 2 counts; nolo contendere to 9 counts by Herman Drug Co., and Gerald P. Herman.

DISPOSITION: 9–30–65. Corporation—$1,000 fine; Herman—$1,000 fine. 1–7–66 Lohmier—2 years' probation.

8624. (F.D.C. No. 51553. S. Nos. 90–072/3 A, 52–282 B.)

INFORMATION FILED: 9–20–65, E. Dist. Pa., against **Harvard Shoostine, t/a Empire Pharmacy, Philadelphia, Pa.**

CHARGE: Between 12–10–64 and 1–13–65, *amphetamine sulfate tablets* were dispensed twice and *secobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–20–66. Probation for 1 year.

8625. (F.D.C. No. 51601. S. Nos. 59–883/4 A, 5–725/8 B.)

INFORMATION FILED: 1–3–66, W. Dist. Mo., against **Robert E. Nigro, Kansas City, Mo.**

CHARGE: Between 12–14–64 and 4–7–65, *amphetamine sulfate tablets* were dispensed 5 times and *amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-28-66. $600 fine, 1 year in prison, plus 5 years' probation.

8626. (F.D.C. No. 51789. S. Nos. 85-512/15 B, 86-451/4 B.)

INFORMATION FILED: 12-13-65, S. Dist. Tex., against **Pablo Garcia and Esteban Villarreal, Edinburg, Tex.**

CHARGE: Between 5-4-65 and 6-25-65, *amphetamine sulfate tablets* were dispensed 3 times, *dextro-amphetamine sulfate capsules* were dispensed twice, and *dextro-amphetamine sulfate tablets* were dispensed once without prescription.

PLEA: Guilty by each to 3 counts.

DISPOSITION: 2-7-66. $150 fine each.

8627. (F.D.C. No. 51591. S. Nos. 60-451/52 A, 60-468 A.)

INDICTMENT RETURNED: 9-16-65, Dist. Nev., against **Aaron Licker and Frank Vincent Esposito, Las Vegas, Nev.**

CHARGE: Between 8-21-64 and 9-15-64, *amphetamine sulfate tablets* were dispensed twice and *Methedrine tablets* once without a prescription.

PLEA: Not guilty by both Licker and Esposito.

DISPOSITION: 2-19-66. After a jury trial Aaron Licker was acquitted on all counts; Frank Esposito was found guilty and sentenced to 9 months in prison.

8628. (F.D.C. No. 51751. S. Nos. 8-690 B, 8-842 B.)

INFORMATION FILED: 11-16-65, Dist. Kans., against **David Lee Shelton, Kansas City, Kans.**

CHARGE: Between 4-29-65 and 5-7-65, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3-10-66. Sentence of 1 year in prison, of which 10 days were to be spent in jail, and 2 years' probation.

8629. (F.D.C. No. 51209. S. Nos. 30-544/5 A, 30-550 A.)

INFORMATION FILED: 10-8-65, E. Dist. Tenn., against **Harry S. Thompson, t/a Harry's Truck Stop, Morristown, Tenn.**

CHARGE: Between 7-27-64 and 8-17-64, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4-4-66. Imprisonment for 1 year of which 335 days were suspended, probation for 3 years, and $2,000 fine.

8630. (F.D.C. No. 51594. S. Nos. 483 X, 2-800 X.)

INFORMATION FILED: 11-17-65, E. Dist. Pa., against **Leonard J. Russock, t/a Russock's Pharmacy, Philadelphia, Pa.**

CHARGE: On 11-8-63 and 11-9-63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4-22-66. $500 fine.

8631. (F.D.C. No. 51964. S. Nos. 14–060/2 B, 85–501/7 B, 86–441 B.)

INFORMATION FILED: 5–5–66, S. Dist. Tex., against **Jose R. Munoz, and Ted Loe, Pharr, Tex., and Alvaro Gonzalez, Edinburg, Tex.**

CHARGE: Between 4–13–65 and 6–11–65, *amphetamine sulfate tablets* were dispensed 7 times and *Dexedrine Spansule capsules* were dispensed 4 times without a prescription.

PLEA: Guilty by Munoz to 7 counts, by Gonzalez to 4 counts, and by Loe to 3 counts.

DISPOSITION: 5–9–66. Munoz and Gonzalez—$100 fine each. 5–23–66. Loe—imprisonment for 1 year suspended, probation for 3 years, and $300 fine.

8632. (F.D.C. No. 51996. S. Nos. 86–901 B, 86–903 B, 86–905/07 B.)

INFORMATION FILED: 4–14–66, N. Dist. Tex., against **Duffie Venus Slaughter, Fort Worth, Tex.**

CHARGE: Between 9–18–65 and 11–23–65, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–16–66. Imprisonment for 1 year suspended, and probation for 2 years.

8633. (F.D.C. No. 51597. S. Nos. 25–429 B, 25–432 B.)

INFORMATION FILED: 9–1–65, E. Dist. Mo., against **Levi D. Denton, M.D., Hayti, Mo.**

CHARGE: Between 3–3–65 and 3–15–65, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–16–66. Imprisonment for 6 months suspended, probation for 1 year, and $1,000 fine, plus costs.

8634. (F.D.C. No. 51218. S. Nos. 24–327 A, 24–337/40 A.)

INFORMATION FILED: 7–14–65, N. Dist. Ill., against **Henry Grady Johnson, Jr., and Carl McMorris, Chicago, Ill.**

CHARGE: Between 7–21–64 and 10–14–64, *amphetamine sulfate tablets* were dispensed 4 times, and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere by Johnson to 5 counts and by McMorris to 1 count.

DISPOSITION: 6–9–66. Johnson—3 years' probation and 50 days in jail, and McMorris—1 year of probation.

8635. (F.D.C. No. 51233. S. No. 137–224 A.)

INFORMATION FILED: 7–9–65, E. Dist. S.C., against **Henry L. (Johnnie) Payne, Charleston Heights, S.C.**

CHARGE: On 11–18–64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–21–66. 1 year in prison, 8 months of which was suspended, and 4 years' probation.

8636. (F.D.C. No. 51602. S. No. 55-271 A.)

INFORMATION FILED: 11-1-65, Dist. Kans., against **John Eldon Kaiser, Wichita, Kans.**

CHARGE: On 11-24-64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 5-10-66, the case came on for trial before court and jury and, on 5-13-66, at the conclusion of the trial, the jury returned a verdict of guilty. On 6-27-66, the court sentenced defendant to imprisonment for 9 months, suspended, probation for 4 years, and $250 fine, plus costs.

8637. (F.D.C. No. 51207. S. No. 59-045 A.)

INFORMATION FILED: 5-20-65, S. Dist. Ill., against **David D. Johnston, Davenport, Iowa. (Violation occurred in Rock Island, Ill.)**

CHARGE: 9-3-64, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-27-66. Probation for 1 year.

8638. (F.D.C. No. 51221. S. Nos. 94-431/2 A, 94-439 A, 95-617/19 A.)

INFORMATION FILED: 7-19-65, E. Dist. Mo., against **Leo Hiken, t/a Union-Easton Drugs, St. Louis, Mo.**

CHARGE: Between 6-29-64 and 7-21-64, *dextro-amphetamine sulfate tablets* were dispensed 4 times, and *secobarbital sodium capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1-20-66. Imprisonment for 6 months and $3,500 fine.

8639. (F.D.C. No. 51767. S. Nos. 85-509/10 B.)

INDICTMENT RETURNED: 12-13-65, S. Dist. Tex., against **Julian Jaimez, Pharr, Tex.**

CHARGE: Between 4-13-65 and 4-22-65, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-7-66. $150 fine.

8640. (F.D.C. No. 51794. S. No. 29-787 B.)

INFORMATION FILED: 10-8-65, Dist. Minn., against **Roger Lee Sheehan, Blaine (Minneapolis), Minn.**

CHARGE: On 9-28-65, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-13-66. $500 fine, and 8 months in jail.

8641. (F.D.C. No. 51953. S. No. 4-658 A.)

INFORMATION FILED: 3-8-66, M. Dist. Ga., against **George M. Harrell (service station employee), Hardwick, Ga.**

CHARGE: On 8-6-64, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 4–21–66, the case came to trial before jury and court, at the conclusion of which the jury rendered a verdict of guilty. On 4–29–66, Harrell was sentenced to imprisonment for 6 months.

8642. (F.D.C. No. 51968. S. Nos. 31–665 B, 31–678 B.)

INFORMATION FILED: 3–16–66, W. Dist. Va., against **Frank S. Sims, Cana, Va.**

CHARGE: On 1–26–65 and 2–10–65, *dextro-amphetamine sulfate capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–18–66. One year imprisonment suspended, and 3 years' probation.

8643. (F.D.C. No. 51979. S. Nos. 55–709 B, 55–712 B, 55–729/30 B, 56–824 B.)

INFORMATION FILED: 4–4–66, W. Dist. Va., against **Charles H. Ross, M.D., Gate City, Va.**

CHARGE: Between 3–17–65 and 7–7–65, *dextro-amphetamine sulfate tablets* were dispensed 4 times, *amphetamine sulfate tablets* were dispensed twice, and capsules containing a *combination of secobarbital sodium and amobarbital sodium* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–26–66. Probation for 3 years.

8644. (F.D.C. No. 51978. S. No. 56–244 B.)

INFORMATION FILED: 4–4–66, S. Dist. W. Va., against **James D. Cottrell, t/a Cottrell's Independent Station, St. Albans, W. Va.**

CHARGE: On 3–23–65, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–27–66. Imprisonment for 1 year.

8645. (F.D.C. No. 50631. S. Nos. 14–061/4 X, 14–066/7 X, 14–069/72 X.)

INFORMATION FILED: 1–5–65, N. Dist. Ill., against **William S. Giles (pharmacist), Chicago, Ill.**

CHARGE: Between 9–13–63 and 11–7–63, *dextro-amphetamine sulfate tablets* were dispensed 6 times, *amobarbital-secobarbital sodium capsules* were dispensed twice, and *apiol and ergot with aloin and pennyroyal capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–24–66. Imprisonment for 10 days and probation for 5 years.

8646. (F.D.C. No. 48517. S. Nos. 676 T, 682/3 T, 76–951/2 T.)

INFORMATION FILED: 2–20–63, N. Dist. Ga., against **William Marvin Tarleton (truck stop employee), Jonesboro, Ga.**

CHARGE: Between 6–7–62 and 6–20–62, *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were dispensed 3 times, and *amphetamine sulfate tablets* were dispensed twice, without a prescription.

PLEA: Guilty.

DISPOSITION: 1–27–65. Imprisonment for 2 years suspended, and probation for 2 years.

8647. (F.D.C. No. 48575. S. Nos. 651 T, 658 T, 76–925 T, 87–801/3 T.)

INFORMATION FILED: 8–22–63, E. Dist. S.C., against **William Andrew Jacobs (truck stop operator), Society Hill, S.C., Fred Burr and Robert Burr (truck stop employees).**

CHARGE: Between 4–15–62 and 7–20–62, *tablets containing a mixture of dextroamphetamine sulfate and amobarbital*, and *amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty by Robert Burr to 2 counts, by Fred Burr to 1 count, and by Jacobs to 1 count.

DISPOSITION: On 12–6–63, Fred Burr and Robert Burr were each sentenced to 1 year in prison, which sentence was suspended, were each sentenced to pay $300 fines and were each placed on probation for 3 years. On 11–17–64, Jacobs was sentenced to imprisonment for 12 months, with a provision for probation for 5 years after service of the first 6 months of imprisonment.

8648. (F.D.C. No. 51775. S. Nos. 11–342/3 A, 55–221 B, 55–227/30 B, 55–233 B.)

INFORMATION FILED: 2–23–66, W. Dist. Va., against **Jan W. Marinus, M.D., and Coenraad Vuurmans, M.D., Fries, Va.**

CHARGE: Between 11–19–64 and 3–11–65, *Adipex tablets* were dispensed 4 times, *Equanil tablets* were dispensed twice, and *pentobarbital sodium capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–11–66. Each defendant—$1,000 fine, and 2 years' probation.

8649. (F.D.C. No. 51050. S. Nos. 13–979 A, 13–980 A, 13–986 A, 15–591/92 A.)

INFORMATION FILED: 3–31–65, Dist. R.I., against **William J. Murphy, t/a Summit Pharmacy, Pawtucket, R.I., and Pasquale Panzarella (pharmacist).**

CHARGE: Between 7–1–64 and 7–28–64, *AM Plus capsules* and *Equanil tablets* were each dispensed twice and *penicillin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–21–66. Murphy—$500 fine; Panzarella—$1,000 fine.

8650. (F.D.C. No. 51321. S. No. 33–793 A.)

INFORMATION FILED: 11–26–65, S. Dist. Ohio, against **Edwin J. Glacken (bar manager), Cincinnati, Ohio.**

CHARGE: On 9–17–64, *Biphetamine T–20 capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–7–66. $500 fine, $400 of which was suspended.

8651. (F.D.C. No. 51038. S. Nos. 73–388/94 A.)

INFORMATION FILED: 4–16–65, S. Dist. Miss., against **Jesse H. Jordan, t/a Meyer-Marx Drug Co., Port Gibson, Miss.**

CHARGE: Between 7–24–64 and 8–5–64, *Equanil tablets* were dispensed 4 times and *penicillin tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 2–9–66. $500 fine, and probation for 5 years.

8652. (F.D.C. No. 50176. S. Nos. 15–193 X, 15–203/4 X, 15–362 X, 16–385 X.)

INFORMATION FILED: 7–13–64, S. Dist. Ohio, against **Ralph H. Donges, t/a William H. Donges Drug Store, Xenia, Ohio, and Harry L. Saberton (pharmacist).**

CHARGE: Between 7–15–63 and 7–22–63, *Equanil tablets* were dispensed 3 times, and *Dexedrine Sulfate tablets* and *Diuril tablets* were each dispensed once without a prescription.

PLEA: Not guilty by Donges to all counts; by Saberton to 1 count involving *Equanil.*

DISPOSITION: On 7–21–64, Donges filed a motion to dismiss the information as to himself on the grounds that he did not participate in any alleged sale, that he was outside the State of Ohio at the time of the alleged sales, and that he had no knowledge of any sales made at Donges Drug Store, Xenia, Ohio, between 7–14–63 and 7–23–63.

On 5–14–65, the court having duly considered the motion of Ralph H. Donges to dismiss the information as to himself, found the motion well taken and sustained the motion. On 6–21–65, Saberton, having originally pleaded not guilty to all counts, changed his plea to guilty to 1 count involving the *Equanil tablets.* On 7–21–65, Saberton was fined $400 on one count; all other counts were dismissed.

8653. (F.D.C. No. 51798. S. Nos. 12–044/5 B, 12–051 B, 12–125 B, 12–127/30 B.)

INFORMATION FILED: 4–15–66, Dist. Utah, against **Frank A. Beckstrom, Payson, Utah.**

CHARGE: Between 3–10–65 and 3–24–65, *Equanil tablets* were dispensed 4 times, *Descillin tablets* were dispensed 3 times, and *penicillin G potassium tablets* were dispensed once, upon requests for prescription refills without authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury, on 6–7–66, and was concluded on the same day with the return of a verdict of guilty and a sentence of 2 years' probation.

8654. (F.D.C. No. 51235. S. Nos. 109–182/84 A.)

INFORMATION FILED: 6–16–65, E. Dist. Ky., against **James E. Croley, t/a Bingham Drug Store, Pineville, Ky.**

CHARGE: Between 8–4–64 and 8–8–64, *Librium Hydrochloride capsules* were dispensed twice, and *Thorazine tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–4–66. $750 fine, plus costs, sentence of 60 days in prison suspended, and probation for 2 years.

8655. (F.D.C. No. 49862. S. Nos. 1–830 X, 1–839 X.)

INFORMATION FILED: 4–28–64, M. Dist. Fla., against **Eckerd's Downtown, Inc., Tom C. Samuels and Frank B. Ham (pharmacists), Orlando, Fla.**

CHARGE: On 8-30-63, *meprobamate tablets* were dispensed twice upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Nolo contendere by Eckerd's Downtown, Inc., to 2 counts; by Ham to 1 count; by Samuels to 1 count.

DISPOSITION: 10-29-65. Corporation—$1,500 fine; individuals—$250 fine each.

8656. (F.D.C. No. 51211. S. Nos. 13-300 A, 15-583 A, 15-586 A, 15-681/82 A, 15-685/87 A.)

INFORMATION FILED: 5-18-65, Dist. Mass., against **Louis Weiner, t/a Lloyd Pharmacy, and Steven N. Tavitian (pharmacist), Watertown, Mass.**

CHARGE: Between 7-3-64 and 9-17-64, *meprobamate tablets* were dispensed 5 times, *Dexedrine Sulfate tablets* were dispensed twice, and *Equanil tablets* were dispensed once upon requests for prescription refills without obtaining authorization from the prescriber.

PLEA: Nolo contendere by Weiner to 8 counts; by Tavitian to 4 counts.

DISPOSITION: 11-29-65. Weiner—$600 fine, 6 months suspended sentence, with 1 year probation; Tavitian—1 year probation.

8657. (F.D.C. No. 51763. S. Nos. 118-204 A, 118-206 A, 6-442 B.)

INFORMATION FILED: 1-13-65, W. Dist. Mo., against **Robert V. Rabinowitz, t/a Ben Casey Sundries, Kansas City, Mo.**

CHARGE: Between 12-7-64 and 1-20-65, *methamphetamine hydrochloride tablets* were dispensed twice and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-4-66. 5 years in prison suspended, and probation for 5 years.

8658. (F.D.C. No. 51596. S. Nos. 4-181/83 B.)

INFORMATION FILED: 10-5-65, E. Dist. Ky., against **Donald Simpson, Richmond, Ky.**

CHARGE: Between 2-4-65 and 2-11-65, *methamphetamine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1-10-66. Imprisonment for 90 days.

8659. (F.D.C. No. 51061. S. Nos. 32-621/22 A.)

INFORMATION FILED: 6-9-65, S. Dist. Ohio, against **Claude Adams, Columbus, Ohio.**

CHARGE: On 8-12-64, *methamphetamine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11-4-65. 18 months in prison.

8660. (F.D.C. No. 51045. S. Nos. 35-372/4 A.)

INFORMATION FILED: 5-10-65, E. Dist. Ky., against **Dean Norman MacDonald, Cincinnati, Ohio.**

CHARGE: Between 10-29-64 and 11-4-64, *methamphetamine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–7–66. Six months in prison.

8661. (F.D.C. No. 49192. S. Nos. 28–843/4 X, 29–891/900 X.)

INFORMATION FILED: 10–29–63, Dist. Nebr., against **Harry G. Williams, M.D., Omaha, Nebr.**

CHARGE: Between 8–15–63 and 9–20–63, *methamphetamine hydrochloride tablets* were dispensed 8 times, and *pentobarbital sodium capsules* were dispensed 4 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–17–65. Imprisonment for 1 year and probation for 2 years.

8662. (F.D.C. No. 51592. S. Nos. 35–388/90 A, 35–392/4 A, 2–184/87 B.)

INFORMATION FILED: 11–2–65, E. Dist. Ky., against **Samuel B. Nunnelley, M.D., Hebron, Ky.**

CHARGE: Between 8–14–64 and 4–13–65, *methamphetamine hydrochloride tablets* were dispensed 8 times, and *phenobarbital tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3–7–66. $1,000 fine and costs suspended, and probation for 1 year.

8663. (F.D.C. No. 50348. S. No. 86–269 V.)

INFORMATION FILED: 7–27–64, N. Dist. Ga., against **Orace David Rice, Decatur, Ga.**

CHARGE: On 4–2–63, *methamphetamine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–1–65. $250 fine, and 2 years' probation.

8664. (F.D.C. No. 51058. S. Nos. 30–970/73 A.)

INFORMATION FILED: 6–9–65, S. Dist. Ohio, against **Frank Lamolinara, Columbus, Ohio.**

CHARGE: Between 8–13–64 and 8–27–64, *methamphetamine hydrochloride tablets* were dispensed 3 times, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: 11–4–65. Defendant was found guilty at a jury trial and sentenced to 18 months in prison.

8665. (F.D.C. No. 51559. S. Nos. 2–921/2 B.)

INFORMATION FILED: 11–29–65, W. Dist. Ky., against **Edward D. Donaldson, Valley Station, Ky.**

CHARGE: On 1–5–65, *methamphetamine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–21–66. $200 fine.

8666. (F.D.C. No. 51606. S. Nos. 4–122 B, 4–124 B.)

INFORMATION FILED: 10–6–65, E. Dist. Ky., against **Herbert Owens, Berea, Ky.**

CHARGE: Between 2-4-65 and 2-10-65, *methamphetamine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1-10-66. 90 days in jail.

8667. (F.D.C. No. 51336. S. No. 23-453 B.)

INFORMATION FILED: 8-10-65, W. Dist. Tex., against **Geraldine Peeler, San Antonio, Tex.**

CHARGE: On 1-12-65, *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-8-65. $250 fine, 1 year in prison suspended, and 3 years' probation.

8668. (F.D.C. No. 51770. S. No. 85-523/24 B.)

INDICTMENT RETURNED: 12-13-65, S. Dist. Tex., against **Fidel Cantu, Rachal, Tex.**

CHARGE: On 5-4-65, *Benzedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-2-66. $100 fine.

8669. (F.D.C. No. 51772. S. Nos. 35-487 B, 35-489 B, 35-492/3 B.)

INFORMATION FILED: 1-11-66, N. Dist. Ind., against **Harry G. Brown, t/a Wilson's Pharmacy, and Russell K. Elisha, Hobart, Ind.**

CHARGE: Between 3-22-65 and 4-22-65, *Nembutal capsules* were dispensed once, *Equanil tablets* were dispensed once, and *Dexedrine Sulfate tablets* were dispensed twice, upon requests for refills of written prescriptions without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3-18-66. Elisha—$150 fine, and probation for 6 months. 7-1-66. Brown—$200 fine, plus costs, and probation for 6 months.

8670. (F.D.C. No. 50645. S. Nos. 6-753/5 X, 6-757/8 X, 6-086 X, 6-987 X, 8-181/2 X, 8-191 X.)

INFORMATION FILED: 4-2-65, Dist. Mass., against **Your Pharmacy (a corporation), Brockton, Mass., George A. Vose (president and treasurer), and Elmer Lindquist (pharmacist).**

CHARGE: Between 8-9-63 and 10-17-63, *Premarin tablets* (counts 4 and 7) were dispensed twice without a prescription; *Miltown tablets* (counts 1, 2, 3, 5, and 8) were dispensed 5 times, and *Dexedrine Spansule capsules* (counts 6, 9, and 10) were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation and Vose to all counts, by Lindquist to counts 2 and 3.

DISPOSITION: On 9-13-65, the corporation was fined $1,000; Vose was fined $500 and placed on probation for 2 years. On 11-8-65, Lindquist was fined $250, which was suspended, and placed on probation for 1 year.

8671. (F.D.C. No. 50453. S. Nos. 96–082 X, 37–562 A, 37–564 A.)

INFORMATION FILED: 12–17–64, N. Dist. Tex., against **Arwine's Pharmacy (a partnership), and George R. Tate (store manager), Lubbock, Tex.**

CHARGE: Between 12–6–63 and 1–8–64, *Preludin (phenmetrazine hydrochloride) tablets*, *Dexedrine Sulfate tablets*, and *Seconal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–13–65. Arwine's Pharmacy—$200 fine; George R. Tate—$300 fine.

8672. (F.D.C. No. 50787. S. Nos. 8–114 X, 8–942/4 X, 8–946/7 X, 93–332/3 X, 93–335 X.)

INFORMATION FILED: 4–2–65, Dist. Mass., against **John L. Tarlow, t/a Tarlow Rexall Drugs, Boston, Mass.**

CHARGE: Between 11–4–63 and 12–2–63, *Premarin tablets* were dispensed once without a prescription, *Equanil tablets* were dispensed 5 times, and *Butisol Sodium tablets* were dispensed 3 times upon requests for prescription refills, without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 12–15–65. Imprisonment for 6 months.

8673. (F.D.C. No. 48920. S. Nos. 63–947 T, 64–472 T.)

INFORMATION FILED: 10–28–64, S. Dist. Fla., against **Mary A. Hepner and Frank P. Santamaria (pharmacists), Miami, Fla.**

CHARGE: Between 8–6–62 and 8–13–62, *penicillin tablets* and *Meticorten tablets* were each dispensed once upon requests for prescription refills without obtaining authorization of the prescriber.

PLEA: Nolo contendere by Hepner and Santamaria to 1 count each.

DISPOSITION: 12–18–64. Each defendant—probation for 6 months.

8674. (F.D.C. No. 51066. S. Nos. 93–701/2 A.)

INFORMATION FILED: 7–1–65, E. Dist. Mo., against **Sidney J. Arkush, t/a Sid's Medical Center Drugs, St. Louis, Mo.**

CHARGE: Between 8–6–64 and 8–10–64, *penicillin tablets* were dispensed twice without prescription.

PLEA: Guilty.

DISPOSITION: 10–1–65. $1,000 fine and 2 years' probation.

8675. (F.D.C. No. 50630. S. Nos. 2–302/5 A, 2–429 A, 2–445/6 A, 2–450/1 A.)

INFORMATION FILED: 12–30–64, M. Dist. Fla., against **Atlantic Beach Drug Stores, Inc., t/a Atlantic Boulevard Drug Stores, Neptune Beach, Fla., Leonard M. Silver (president and treasurer), and Gilbert N. Weise (pharmacist).**

CHARGE: Between 1–27–64 and 4–6–64, *penicillin tablets* were dispensed 4 times, *Dexedrine Spansule capsules* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed twice upon requests for prescription refills without authorization of the prescriber.

PLEA: Not guilty.

DISPOSITION: On 3–23–65, the defendants filed a motion to dismiss and a motion for a bill of particulars. The defendants' motion for a bill of particulars moved to require the Government to inform the defendants as follows:

1. To state the exact date on which each alleged offense was committed.

2. To state particularly in what manner and how each of the defendants participated in each of said offenses.

3. To state the manner and in what respect each drug described in each count of the Information was misbranded while held for sale.

4. To identify each person or persons who actually refilled each of the prescriptions set forth in each count of the Information.

5. To set forth the name and address of each physician from whom the defendants failed to obtain authorization in refilling the written prescriptions.

On 5–20–65, the court denied the defendants' motion to dismiss, denied the defendants' motion for a bill of particulars with respect to the above paragraphs 1 and 2, and granted the defendants' bill of particulars with respect to paragraphs 3, 4, and 5.

On 6–7–65, the case came on for trial before the court and jury. On 6–9–65, the jury returned a verdict of not guilty as to the corporation and Gilbert N. Weise, and of guilty with respect to Leonard M. Silver with respect to 5 counts only. On 6–9–65, Silver was fined $1,000 and sentenced to 1 year imprisonment which sentence was suspended.

8676. (F.D.C. No. 51024. S. Nos. 44–842 A, 44–844 A, 44–846 A, 44–851/2 A.)

INFORMATION FILED: 2–25–65, Dist. Colo., against **Littleton Drug Store, Inc., Henry L. Feistner (president-pharmacist), and Robert E. Crocker (pharmacist), Littleton, Colo.**

CHARGE: Between 2–16–64 and 7–14–64, *pentobarbital sodium capsules* were dispensed twice and *Metandren tablets* were dispensed once upon requests for prescription refills without obtaining authorization from the prescriber, and *penicillin G potassium tablets* were dispensed twice without a prescription.

PLEA: Guilty by corporation to 1 count, by Feistner to 2 counts, and by Crocker to 2 counts.

DISPOSITION: 12–2–65. Corporation—$500 fine; Feistner—$400 fine, and 2 years' probation; and Crocker—$200 fine, and 2 years' probation.

8677. (F.D.C. No. 51778. S. No. 56–221 B.)

INFORMATION FILED: 10–28–65, S. Dist. W. Va., against **Robert B. Meek, M.D., Gordon, W. Va.**

CHARGE: On 1–27–65, *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–1–66. 1 year in prison.

8678. (F.D.C. No. 51749. S. Nos. 16–323/6 A, 16–331 A, 16–528 A, 16–530/3 A.)

INFORMATION FILED: 11–3–65, Dist. Mass., against **Munroe Drug Co., Inc., t/a Munroe Drug Co., Lynn, Mass., and Melvin J. Bloom (treasurer).**

CHARGE: Between 10–15–64 and 12–15–64, *Seconal Sodium capsules* were dispensed 3 times, *Dexedrine Spansule capsules* were dispensed 3 times, and *Librium Hydrochloride capsules* were dispensed twice, upon request for prescription refills without authorization from the prescriber; and *Equanil tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–18–66. Corporation—$1,000 fine; individual—$6,000 fine, imprisonment for 6 months suspended, and probation for 2 years.

8679. (F.D.C. No. 51783. S. Nos. 30–635 B, 30–653 B, 30–657 B, 30–663 B, 30–672 B, 32–798 B, 33–431 B.)

INFORMATION FILED: 1–27–66, M. Dist. N.C., against **Baxter's Drug Store, Inc., Kannapolis, N.C., and Thomas R. Bostian (pharmacist).**

CHARGE: Between 2–18–65 and 6–14–65, *Miltown tablets* were dispensed 5 times and *Librium Hydrochloride capsules* were dispensed twice, upon requests for prescription refills without authorization from the prescriber.

PLEA: Not guilty by corporation to 7 counts; by individual to 6 counts.

DISPOSITION: On 4–22–66, the case came to trial before the court; and after the trial on that day, the court found the defendants guilty and fined the corporation $875, of which $500 was suspended, and the individual $750, of which $500 was suspended.

8680. (F.D.C. No. 51799. S. Nos. 17–522 A, 17–524 A, 43–082 B, 43–092 B, 43–362 B, 43–365/6 B, 43–722 B.)

INFORMATION FILED: 2–3–66, Dist. Mass., against **Western Refining Co., Inc., t/a Peikes Pharmacy, Lowell, Mass., Harold Levin (president and treasurer), and Robert E. Bagshaw (pharmacist).**

CHARGE: Between 12–14–64 and 3–2–65, *Miltown tablets* were dispensed 4 times (counts 1, 2, 3, and 4), *Dexedrine Sulfate tablets* were dispensed 3 times (counts 5, 6, and 8) and *Librium Hydrochloride capsules* were dispensed once (count 7), upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation and Levin to all counts; by Bagshaw to counts 3, 5, 6, and 7.

DISPOSITION: 5–9–66. Corporation—$500 fine; Levin—imprisonment for 3 months suspended, probation for 1 year, and $250 fine; Bagshaw—imprisonment for 3 months suspended, and probation for 1 year.

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PRODUCTS

[1](8621, 8627, 8636, 8641, 8652, 8653, 8664, 8675, 8679) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (8621, 8627, 8636, 8641, 8652, 8653, 8664, 8675, 8679) Prosecution contested.

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U.S. GOVERNMENT PRINTING OFFICE: 1967

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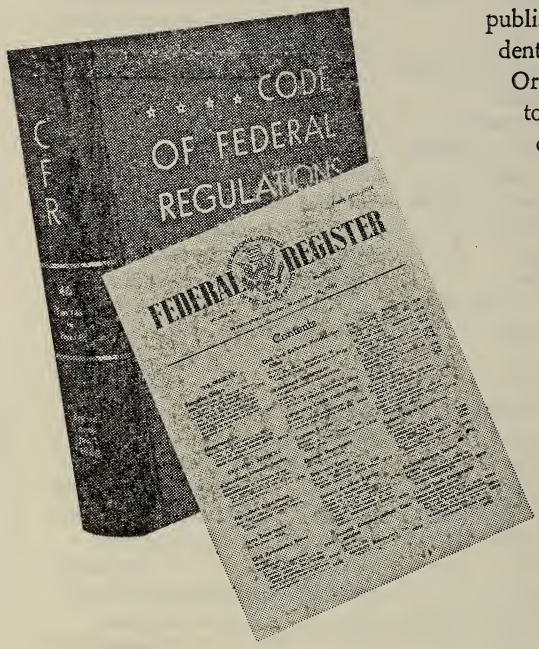

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